TRANSCRIPT OF RECORD.

SUPREME COURT OF THE UNITED STATES.

OCTOBER TERM, 1911.

No. ~~836~~. 118

THE UNITED STATES OF AMERICA, PLAINTIFF IN ERROR AND APPELLANT,

vs.

THE ANTIKAMNIA CHEMICAL COMPANY.

IN ERROR TO AND APPEAL FROM THE COURT OF APPEALS OF THE DISTRICT OF COLUMBIA.

FILED OCTOBER 17, 1911.

(22,912.)

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INDEX.

JUDD & DETWEILER (INC.), PRINTERS, WASHINGTON, D. C., OCTOBER 30, 1911.

Act of Congress in such case made and provided, approved June thirtieth, A. D. 1906 (Part 1, Vol. 34, U. S. Statutes at Large, p. 738, commonly known as the Food and Drugs Act).

2 II.

Your libelant represents to this Honorable Court that in the City of Washington, in the District of Columbia, and within the jurisdiction of this Honorable Court, are, to wit, one hundred packages, more or less, of a certain drug used and intended to be used for the cure and mitigation and prevention of disease of man, particularly described as follows:

Twenty packages, more or less, of said drug, labelled and branded as follows: "Antikamnia Tablets. Contain 305 grains of acetphenetidin, U. S. P. per ounce. Guaranteed by the Antikamnia Chemical Company, under the Food and Drugs Act, June 30, 1906. U. S. Serial Number 10. The Antikamnia tablets in this original ounce package contain no acetanilid, antifebrin, antipyrin, morphine, opium, codein, heroin, cocaine, alpha or beta eucaine, arsenic, strychnine, chloroform, cannabis indica, or chloral hydrate. Antikamnia tablets five grains. One ounce Antikamnia Tablets. Manufactured in the United States of America by the Antikamnia Chemical Co., St. Louis, U. S. A."

Also seventy other packages, more or less, of said drug, labelled and branded as follows: "Antikamnia and Codein Tablets. Contain 296 grains acetphenetidin, U. S. P. per ounce. Contain 18 grains sulp. codein per ounce. Guaranteed by the Antikamnia Chemical Company, under the Food and Drugs Act, June 30, 1906, U. S. Serial number 10. The Antikamnia and Codein tablets in this original ounce package contain no acetanilid, antifebrin, antipyrin, morphine, opium, heroin, cocaine, alpha, or beta eucaine, arsenic, strych-ine, chloroform, cannabis indica, or chloral hydrate. One ounce Antikamnia and Codein Tablets. Manufactured in the United States of America by the Antikamnia Chemical Co., St. Louis, U. S. A."

Also ten other packages, more or less, of said drug, labelled and branded as follows: "Antikamnia and Quinine Tablets. Contain 165 grains acetphenetidin, U. S. P. per ounce. Guaranteed by the Antikamnia Chemical Company, under the Food and Drugs Act, June 30, 1906, U. S. Serial Number 10. The Antikamnia and Quinine Tablets in this original ounce package contain no acetanilid, antifebrin, antipyrin, morphine, opium, codein, heroin, cocaine, alpha or beta eucaine, arsenic, strych-ine, chloroform, cannabis indica, or chloral hydrate. One ounce Antikamnia and Quinine Tablets. Manufactured in the United States of America by the Antikamnia Chemical Co., St. Louis, U. S. A."

Your libelant further represents that the said one hundred packages, more or less, particularly described as aforesaid, are now in the possession and custody of The Washington Wholesale Drug Exchange, a body corporate, at premises, to wit, numbered four hundred and fifty-nine on C Street, North-west, in the City of Washington, District of Columbia.

III.

Your libelant further represents that the said one hundred packages, more or less, of said drug, as aforesaid particularly described, are illegally held within the jurisdiction of this Honorable Court, for that the same are misbranded in violation of the aforesaid Act of Congress approved June thirtieth, A. D. 1906, and are
3 liable to confiscation and condemnation as provided therein, for the reasons following:

Because each and all of said packages of drug contain a large quantity and proportion of acetphenetidin, which your libelant charges is a derivative of acetanilid, and that under the provisions of the said Act of Congress and of the regulations lawfully made thereunder, it is provided and required that the label on each of said packages should bear a statement that the acetphenetidin contained therein is a derivative of acetanilid; and yet your libelant charges that each and all of said packages fail to bear a statement in any form that the acetphenetidin contained therein is a derivative of acetanilid, or that the said drug contains any derivative of acetanilid.

Your libelant further charges that each and all of said packages of drug are further misbranded, in that the labels thereon are false and misleading, for the reason that each and all of said labels bear the statement that no acetanilid is contained therein, and that said statement imports and signifies that there is no quantity or proportion of any derivative of acetanilid contained in said drug.

IV.

Your libelant further represents that all the matters above set forth are true; that the said packages of said drug are now in the possession and custody of the said The Washington Wholesale Drug Exchange, a body corporate, as aforesaid, at the premises aforesaid, and are now being sold and offered for sale by said body corporate within the District aforesaid.

Wherefore, the premises considered, your libelant prays:

1. That the said packages of said drug be proceeded against and seized for condemnation in accordance with the provisions of the said Act of Congress, and that to this end this Honorable Court may order a warrant of arrest to issue in due form of law, according to the course of this Honorable Court in cases of admiralty, so far as is applicable in this case, and that the said The Washington Wholesale Drug Exchange, a body corporate, and all other persons having or pretending to have any right, title or claim in and to the said drug, may be cited to appear herein and answer all and singular the premises aforesaid.

2. That by a proper order this Honorable Court may adjudge and decree that the said packages of said drug and each and all thereof be condemned at the suit of this libelant, according to the provisions of the said Act of Congress; and that the same may be disposed of by sale, under such terms and conditions as this Honorable Court, by a proper order shall provide; and that the proceeds thereof, less legal

costs and charges, by a proper order, may be directed to be paid into the Treasury of the United States.

3. That this Honorable Court may pass all such orders, decrees and judgments as may be necessary in the premises, and may grant your libelant a decree for the costs of this proceeding, against the owners or the holders of said drug so condemned, should such costs not be paid out of the proceeds of the sale of same, or otherwise.

And that your libelant may have such other and further
4 relief as the nature of the case may require.

CLARENCE R. WILSON,
Attorney of the United States in and
for the District of Columbia.

DISTRICT OF COLUMBIA, *ss:*

I, Clarence R. Wilson, being first duly sworn, on oath say that I am the Attorney of the United States in and for the District of Columbia; that I have read over the foregoing libel by me subscribed, and know the contents thereof; that the matters and things therein stated of my own knowledge are true, and those stated on information and belief I believe to be true.

CLARENCE R. WILSON.

Subscribed and sworn to before me this 7 day of July, A. D. 1910.

J. R. YOUNG, *Clerk,*
By R. P. BELEW, *Asst. Clerk.*

Endorsed: Let the warrant issue herein as prayed, returnable on the 4th day of August, A. D. 1910, at 10:30 A. M.

WENDELL P. STAFFORD, *Justice.*

Warrant of Arrest.

Filed Jul- 12, 1910.

* * * * * * *

The President of the United States to the Marshal for said District, Greeting:

For the reasons stated in the Libel, herein filed on the 7th day of July 1910, by Clarence R. Wilson, U. S. Attorney, D. C.

You are hereby commanded to arrest the said 20 packages, more or less, labeled "Antikamnia Tablets; the said 70 packages, more or less, labeled "Antikamnia and Codein Tablets", and the said 10 packages, more or less, labeled "Antikamnia and Quinine Tablets", in possession and on premises of The Washington Wholesale Drug Exchange, 459 C Street, N. W., Washington, D. C. and detain the same until further order of the Court; and to warn all persons having any claim or interest therein, to be and appear before said Court on the 4th day of August 1910, at 10.30 A. M., to answer said libel;

and that in case of failure to appear the Court will proceed to determine the cause, and to make such order therein as to it shall seem right.

Witness The Honorable Harry M. Clabaugh, Chief Justice of said Court, the 7th day of July, A. D. 1910.

[SEAL.]

J. R. YOUNG, *Clerk*,
By F. E. CUNNINGHAM,
Assistant Clerk.

_____,
U. S. Attorney.

5

Marshal's Return.

Arrested 20 packages labeled Antikamnia Tablets, 10 packages labeled Antikamnia and Quinine Tablets and 63 packages labeled Antikamnia and Codein Tablets and in custody. Served copy of the writ on the Washington Wholesale Drug Exchange by service on Wymond H. Bradbury, Manager, personally and tacked a copy of the writ on the Court House door all this 7th day of July 1910.

AULICK PALMER, *Marshal*.
H.

Petition.

Filed Oct. 3, 1910.

* * * * * * *

Your petitioner, the Antikamnia Chemical Company, respectfully represents:

First. That it is a corporation duly incorporated.

Second. That it is the true and bona fide owner of the several packages of tablets mentioned in the second paragraph of the libel filed in the above entitled cause, and that no other person is the owner thereof, and that as such owner, it desires to intervene and be made a defendant in said libel in order that it may protect its rights to the said packages mentioned in said second paragraph of said libel.

Wherefore, your petitioner prays that this honorable Court pass an order, making your petitioner a defendant in said suit and giving to your petitioner all rights that it may have as such defendant to raise questions of law and fact in said suit, and such other and further relief as this petition may require.

THE ANTIKAMNIA CHEMICAL CO.,
By FRANK A. REEF, *President*.

BAKER, SHEEHY & HOGAN,
Attorneys for Petitioner.

Frank A. Reef, being first duly sworn, deposes and says that he is the President of The Antikamnia Chemical Company, petitioner

in the above entitled cause, and that he has read said petition and that the facts therein stated are true.

FRANK A. REEF.

Subscribed and sworn to before me this first day of October, A. D. 1910.

[SEAL.] JAMES J. McDONALD.
Notary Public in and for the City of St. Louis, Mo.

My term expires Sept. 28, 1912.

Order.

Filed Oct. 3, 1910.

* * * * * * *

Upon consideration of the petition of The Antikamnia Chemical Company, it is this 3rd day of October 1910,

6 Ordered that the said petitioner, The Antikamnia Chemical Company, be and it is hereby made a defendant in the above entitled cause with full rights to litigate any questions that may arise therein.

By the Court.

HARRY M. CLABAUGH.
Chief Justice.

Exceptions to Libel.

Oct. 3, 1910.

* * * * * * *

Now comes the defendant, The Antikamnia Chemical Company, owner of the packages mentioned in the second paragraph of the libel filed in the above entitled cause, and objects and excepts to the seizure of the several packages mentioned in said libel, and objects and excepts to the said libel and says that the said libel is bad in substance and does not contain any statement of fact or allegation to warrant the seizure of the said packages mentioned in said libel and the condemnation thereof because the said defendant severally says:

1. That said packages referred to in said libel are not misbranded in violation of the Act of Congress approved June 30, 1906, entitled "The Food and Drugs Act," and are not liable to confiscation and condemnation under said Act, because each and all of said packages are properly marked and properly state the proportion of acetphenetidin contained therein and that they are properly labeled under said Act.

2. That the said Act does not require that the label on each of said packages should bear a statement that the acetphenetidin contained therein is a derivative of acetanilid, nor is it necessary under said Act that a derivative of any parent substance should state that

it is a derivative of such substance, provided the derivative itself is named by its proper name.

3. That the said packages are not misbranded, in that each and all of the said labels bear the statement that no acetanilid is contained therein because, according to the allegation of said libel, there is nothing in said statement that is in any way false and misleading, nor does said statement import or signify that there is no quantity or proportion of any derivative of acetanilid contained in said drug.

4. That said statement on said packages that each and all of said labels bear the statement that no acetanilid is contained therein is in no way false or misleading, because said libel does not allege that there is any acetanilid in said packages, and, therefore, said statement, instead of being false and misleading, is, according to the allegations of said libel, true.

5. That said libel does state that in said packages is contained acetphenetidin and the other statement on said package that said package contains no acetanilid could in no way be false and misleading because, according to the allegations of said libel, the same is true.

7 6. That said libel charges that acetphenetidin is a derivative of acetanilid, but does not charge that there is any acetanilid in acetphenetidin and, therefore, the statement as contained on the label of said packages, that there is no acetanilid contained in said packages, is, according to the averments and allegations of said libel, true.

7. That said Act of Congress of June 30, 1906, provides in section 8:

"* * * or if the package fail to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any such substances contained therein."

And does not provide that there should be added to any derivative of any such substance as contained therein the name of said parent substance and said Act of Congress cannot be added to or enlarged by requiring this defendant, or any person, to add to a known substance the fact that the same is a derivative of any of the substances mentioned in the above paragraph.

8. Defendant further objects and excepts to the following paragraph in section 3 of said libel:

"Because each and all of said packages of drug contain a large quantity and proportion of acetphenetidin, which your libelant charges is a derivative of acetanilid, and that under the provisions of the said Act of Congress and of the regulations lawfully made thereunder, it is provided and required that the label on each of said packages should bear a statement that the acetphenetidin contained therein is a derivative of acetanilid; and yet your libelant charges that each and all of said packages fail to bear a statement in any form that the acetphenetidin contained therein is a derivative of acetanilid, or that the said drug contains any derivative of acetanilid."

And says that same is bad in substance because there is nothing in said Act of Congress, approved June 30, 1906, that requires the labeling of the said packages as set out in said paragraph.

9. Defendant further objects and excepts to the following paragraph in section 3 of said libel:

"Your libelant further charges that each and all of said packages of drug are further misbranded, in that the labels thereon are false and misleading, for the reason that each and all of said labels bear the statement that no acetanilid is contained therein, and that said statement imports and signifies that there is no quantity or proportion of any derivative of acetanilid contained in said drug."

And says that the same is bad in substance because it says that in said libel there is no allegation, either direct or indirect, that there is any acetanilid contained in said drug, and because the statement that there is no acetanilid contained in said drug in no way imports or signifies that there is no quantity or proportion of a derivative of acetanilid.

Wherefore, your defendant prays that the said exceptions and objections to said libel be severally sustained, that said libel be dismissed and said packages mentioned in said libel be restored
8 to your petitioner as the owner thereof, and that costs be awarded against the United States for unlawfully seizing the said packages.

BAKER, SHEEHY & HOGAN,
Attorneys for Defendant.

Decree.

Filed Nov. 21, 1910.

* * * * * * *

This cause coming on to be heard upon the libel and the exceptions and objections filed thereto, and the same having been argued by counsel for the respective parties, and having been fully considered by the court, it is this 21st day of November, A. D. 1910,

Ordered, adjudged and decreed: That said exceptions and objections to said libel be, and the same are, hereby sustained, and that the said libel be, and the same is, hereby dismissed, and that the goods seized be, and the same are, hereby discharged from said seizure and ordered returned to the Defendant, the Antikamnia Chemical Company, without cost to the Defendant.

HARRY M. CLABAUGH,
Chief Justice.

From this decree the United States, in open court pray an appeal to the Court of Appeals, which is hereby granted, this 21st day of November, 1910, and it is hereby ordered that, pending said appeal, the said goods remain in the custody of the Marshal.

HARRY M. CLABAUGH,
Chief Justice.

Stipulation.

Filed Dec. 7, 1910.

* * * * * * *

It is hereby stipulated and agreed by and between Clarence R. Wilson, Attorney of the United States in and for the District of Columbia, on behalf of the United States of America, libelants, and Daniel W. Baker, attorney for the claimant in the above entitled cause, that Food Inspection Decision No. 112, issued January 27, 1910, by the United States Department of Agriculture, was considered by this Court upon the hearing of the above cause, and that the said Food Inspection Decision shall be included in and considered as a part of the record of this cause on appeal, this Court having taken judicial notice thereof.

CLARENCE R. WILSON,
Attorney of the United States in and for the District of Columbia.

DANIEL W. BAKER,
Attorney for Claimant.

9 F. I. D. 112. Issued January 27, 1910.

UNITED STATES DEPARTMENT OF AGRICULTURE,
OFFICE OF THE SECRETARY,
BOARD OF FOOD AND DRUG INSPECTION.

Food Inspection Decision 112.

Amendment to Regulation 28 (Labeling of Derivatives).

Section 8 of the Food and Drugs Act of June 30, 1906, paragraph "Second," under "Drugs," provides that a drug shall be deemed to be misbranded "if the package fail to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any such substances contained therein."

In an opinion rendered January 15, 1909, the Attorney-General held that a derivative within the meaning of this section of the act is a substance which is so related to one of the specified substances "that it would be rightly regarded by recognized authorities in chemistry as obtained from the latter 'by actual or theoretical substitution,' and it is not indispensable that it should be actually produced therefrom as a matter of fact," and, further, that the labeling of derivatives, as prescribed by this section, is a proper subject conferred upon them by section 3, and that a rule or regulation requiring the name of the specified substance to follow that of the derivative would be in harmony with the general purpose of the act, and an appropriate method by which to give effect to its provisions.

In conformity with this opinion, the Board of Food and Drug Inspection recommends that Regulation 28 of the Rules and Regulations for the enforcement of the Food and Drugs Act, published in Circular 21 of the Office of the Secretary, be amended by the addition, to follow paragraph (*f*), of a new paragraph to be designated as paragraph (*g*), reading as follows:

(*g*) In declaring the quantity or proportion of any of the specified substances the names by which they are designated in the act shall be used, and in declaring the quantity or proportion of derivatives of any of the specified substances, in addition to the trade name of the derivative, the name of the specified substance shall also be stated, so as to indicate clearly that the product is a derivative of the particular specified substance.

10 This paragraph (*g*) prescribes, in effect, that in labeling derivatives the name of the specified substance must be stated, so as to clearly indicate that the product is a derivative of the particular substance named in the act.

Regulation 28 as amended shall be effective on and after April 1, 1910, and the regulation in full shall read as follows:

Regulation 28.—*Substances Named in Drugs or Foods.*

(Section 8, Second under "Drugs"; Second under "Foods.")

(*a*) The term "alcohol" is defined to mean common or ethyl alcohol. No other kind of alcohol is permissible in the manufacture of drugs except as specified in the United States Pharmacopœia or National Formulary.

(*b*) The words alcohol, morphine, opium, etc., and the quantities and proportions thereof, shall be printed in letters corresponding in size with those prescribed in Regulation 17, paragraph (*c*).

(*c*) A drug, or food product, except in respect of alcohol, is misbranded in case it fails to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, heroin, cocaine, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any such substances contained therein.

(*d*) A statement of the maximum quantity or proportion of any such substances present will meet the requirements, provided the maximum stated does not vary materially from the average quantity or proportion.

(*e*) In case the actual quantity or proportion is stated it shall be the average quantity or proportion with the variations noted in Regulation 29.

(*f*) The following are the principal derivatives and preparations made from the articles which are required to be named upon the label:

Alcohol, Ethyl (cologne spirits, grain alcohol, rectified spirits, spirits, and spirits of wine).

Derivatives—Aldehyde, ether, ethyl acetate, ethyl nitrite, and paraldehyde.

Preparations containing alcohol—Bitters, brandies, cordials, elixirs, essences, fluid extracts, spirits, sirups, tinctures, tonics, whiskies, and wines.

Morphine, Alkaloid:

Derivatives—Apomorphine, dionine, peronine, morphine, acetate, hydrochloride, sulphate, and other salts of morphine.

Preparations containing morphine or derivatives of morphine—Bougies, catarrh snuff, chlorodyne, compound powder of morphine, crayons, elixirs, granules, pills, solutions, sirups, suppositories, tablets, triturates, and troches.

Opium Gum:

Preparations of opium—Extracts, denarcotized opium, granulated opium, and powdered opium, bougies, brown mixture, carminative mixtures, crayons, dover's powder, elixirs, liniments, ointments, paregoric, pills, plasters, sirups, suppositories, tablets, tinctures, troches, vinegars, and wines.

Derivatives—Codeine, alkaloid, hydrochloride, phosphate, sulphate, and other salts of codein.

Preparations containing codein or its salts—Elixirs, pills, sirups, and tablets.

U-12 Cocaine, Alkaloid:

Derivatives—Cocaine hydrochloride, oleate, and other salts.

Preparations containing cocaine or salts of cocaine—Coca leaves, catarrh powders, elixirs, extracts, infusion of coca, ointments, paste, pencils, pills, solutions, sirups, tablets, tinctures, troches, and wines.

Heroin:

Preparations containing heroin—Sirups, elixirs, pills, and tablets.

Alpha and Beta Eucaine:

Preparations—Mixtures, ointments, powders, and solutions.

Chloroform:

Preparations containing chloroform—Chloranodyne, elixirs, emulsions, liniments, mixtures, spirits, and sirups.

Cannabis Indica:

Preparations of cannabis indica—Corn remedies, extracts, mixtures, pills, powders, tablets, and tinctures.

Chloral Hydrate (Chloral, U. S. Pharmacopœia, 1890):

Derivatives—Chloral acetophenonoxim, chloral alcoholate, chloralamide, chloralimide, chloral orthoform, chloralose, dormiol, hypnal, and uraline.

Preparations containing chloral hydrate or its derivatives—Chloral camphorate, elixirs, liniments, mixtures, ointments, suppositories, sirups, and tablets.

Acetanilide (Antifebrine, Phenylacetamide):

Derivatives—Acetphenetidine, citrophen, diacetanilide, lactophenin, methoxy-acetanilide, methylacetanilide, para-iodoacetanilide, and phenacetine.

Preparations containing acetanilide or derivatives—Analgesics, antineuralgics, antirheumatics, cachets, capsules, cold remedies, elixirs, granular effervescing salts, headache powders, mixtures, pain remedies, pills, and tablets.

(*g*) In declaring the quantity or proportion of any of the specified substances the names by which they are designated in the act shall be used, and in declaring the quantity or proportion of derivatives of any of the specified substances, in addition to the trade name of the derivative, the name of the specified substance shall also be stated, so as to indicate clearly that the product is a derivative of the particular specified substance.

H. W. WILEY,
F. L. DUNLAP,
GEO. P. McCABE,
Board of Food and Drug Inspection.

Approved:

FRANKLIN MacVEAGH,
Secretary of the Treasury.
JAMES WILSON,
Secretary of Agriculture.
CHARLES NAGEL,
Secretary of Commerce and Labor.

Washington, D. C., January 6, 1910.

13 *Directions to Clerk for Preparation of Transcript of Record.*

Filed Dec. 7, 1910.

* * * * * * *

The Clerk of the Court will please prepare transcript of record in the above entitled cause, and include therein the following:

1. Libel filed July 7, 1910, and fiat.
2. Warrant of Arrest and Marshal's return thereon.
3. Petition of owner to be made defendant, and order thereon, filed October 3, 1910.
4. Exceptions to libel, filed October 3, 1910.
5. Decree sustaining exceptions and dismissing libel; appeal noted in open court by libelants, and order of court thereon, filed November 21, 1910.
6. Stipulation as to record, and Food Inspection Decision 112, filed Dec. 7, 1910.
7. This designation.

CLARENCE R. WILSON,
Attorney of the United States in and for the District of Columbia.

The foregoing is satisfactory.

DANIEL W. BAKER,
Attorneys for Claimant.

Supreme Court of the District of Columbia.

UNITED STATES OF AMERICA,
District of Columbia, ss:

I, John R. Young, Clerk of the Supreme Court of the District of Columbia, hereby certify the foregoing pages numbered from 1 to 18, both inclusive, to be a true and correct transcript of the record, according to directions of counsel herein filed, copy of which is made part of this transcript, in cause entitled The United States of America, libelant, vs. One Hundred Packages, more or less of "Antikamnia Tablets," No. 883, District Court Docket, as the same remains upon the files and of record in said Court.

In testimony whereof, I hereunto subscribe my name and affix the seal of said Court, at the City of Washington, in said District, this 15th day of December, 1910.

[Seal Supreme Court of the District of Columbia.]

JOHN R. YOUNG, *Clerk.*

Endorsed on cover: District of Columbia Supreme Court. No. 2257. The United States of America, appellant, vs. The Antikamnia Chemical Company. Court of Appeals, District of Columbia. Filed Dec. 19, 1910. Henry W. Hodges, clerk.

14

No. 2257.

THE UNITED STATES OF AMERICA, Appellant,
vs.
THE ANTIKAMNIA CHEMICAL COMPANY.

FRIDAY, *April 7th*, A. D. 1911.

The argument in the above entitled cause was commenced by Mr. S. C. Peele, attorney for the appellant, and was continued by Mr. D. W. Baker, attorney for the appellee.

No. 2257.

THE UNITED STATES OF AMERICA, Appellant,
vs.
THE ANTIKAMNIA CHEMICAL COMPANY.

MONDAY, *April 10th*, A. D. 1911.

The argument in the above entitled cause was continued by Mr. D. W. Baker, attorney for the appellee, and was concluded by Mr. Clarence R. Wilson, attorney for the appellant.

On motion the appellee is allowed five days to file an additional brief herein if so advised.

15 No. 2257.

UNITED STATES OF AMERICA, Appellant,
v.
ANTIKAMNIA CHEMICAL COMPANY.

Opinion.

Mr. Chief Justice Shepard delivered the opinion of the Court:

This is an appeal by the United States from a judgment sustaining exceptions to, and dismissing a libel.

The libel prayed the seizure and condemnation of one hundred packages of a certain drug describing the same as follows:

Twenty packages, more or less, of said drug, labelled and branded as follows: "Antikamnia Tablets. Contain 305 grains of acetphenetidin, U. S. P. per ounce, Guaranteed by the Antikamnia Chemical Company, under the Food and Drugs Act, June 30th, 1906, U. S. Serial Number 10. The Antikamnia Tablets in this original ounce package contain no acetanilid, antifebrin, antipyrin, morphine, opium, codein, heroin, cocaine, alpha or beta eucaine, arsenic, strychnine, chloroform, cannabis indica, or chloral hydrate. Antikamnia Tablets five grains. One ounce Antikamnia Tablets. Manufactured in the United States of America by the Antikamnia Chemical Company, St. Louis, U. S. A."

Also seventy other packages, more or less, of said drug, labelled and branded as follows: "Antikamnia and Codein Tablets. Contain 296 grains acetphenetidin, U. S. P. per ounce. Contain 18 grains supl. codein per ounce. Guaranteed by the Antikamnia Chemical Company, under the Food and Drugs Act, June 30th, 1906, U. S. Serial No. 10. The Antikamnia and Codein Tablets in this original ounce package contain no acetanilid, antifebrin, antipyrin, morphine, opium, heroin, cocaine, alpha or beta eucaine, arsenic, strychnine, chloroform, cannabis indica, or chloral hydrate. One ounce Antikamnia and Codein Tablets. Manufactured in the United States of America by the Antikamnia Chemical Company, St. Louis, U. S. A."

Also ten other packages, more or less, of said drug, labelled and branded as follows: "Antikamnia and Quinine Tablets. Contain 165 grains acetphenetidin, U. S. P. per ounce. Guaranteed by the Antikamnia Chemical Company, under the Food and Drugs Act, June 30th, 1906, U. S. Serial No. 10. The Antikamnia and Quinine Tablets in this original ounce package contain no acetanilid, antifebrin, antipyrin, morphine, opium, codein, heroin, cocaine, alpha or beta eucaine, arsenic, strychnine, chloroform, cannabis indica, or chloral hydrate. One ounce Antikamnia and Quinine Tablets. Manufactured in the United States of America by the Antikamnia Chemical Company of St. Louis, U. S. A."

The libel charges that the packages of said drug are subject to condemnation as misbranded in violation of the provisions of the Food and Drugs Act, approved June 30, 1906.

"Because each and all of said packages of drug contain a large quantity and proportion of acetphenetidin, which your libelant charges is a derivative of acetanilid, and that under the provisions of the said act of Congress and of the regulations lawfully made thereunder, it is provided and required that the label on each of said packages should bear a statement that the acetphenetidin contained therein is a derivative of acetanilid; and yet your libelant charges that each and all of said packages fail to bear a statement in any form that the acetphenetidin contained therein is a derivative of acetanilid, or that the drug contains any derivative of acetanilid.

"Your libelant further charges that each and all of said packages of drug are further misbranded in that the labels thereon are false and misleading, for the reason that each and all of the said labels bear the statement that no acetanilid is contained therein, and that said statement imports and signifies that there is no quantity or proportion of any derivative of acetanilid contained in said drug."

Under the warrant ordered to issue, the marshal seized ninety-three packages in all bearing the labels aforesaid. By leave of the court, the Antikamnia Chemical Company, alleging itself to be the owner of the packages, was permitted to appear as party defendant.

The exceptions on which the libel was dismissed are substantially: That the act does not require that the label on each of said packages shall have a statement that the acetphenetidin contained therein is a derivative of acetanilide, nor is it necessary under said act that a derivative of any parent substance should state that it is a derivative of such substance, provided the derivative itself is named by its proper name. That the statement on the packages that it contains no acetanilid is neither false nor misleading, but true, and the libel while charging that acetphenetidin is a derivative of acetanilide, does not charge that there is any acetanilide in acetphenetidin.

Section 1 of the Food and Drugs Act makes it unlawful to manufacture within any territory, or the District of Columbia, an article of Food or Drug which is adulterated or misbranded, "within the meaning of this act," and imposes a penalty therefor.

16 Section 2 prohibits the introduction into any State or Territory, or the District of Columbia, and the shipment from the same to any other State, Territory, etc., or foreign country, any article of food or drug, in the original packages, adulterated or misbranded within the meaning of this act, and the sale or offer for sale in the District of Columbia or Territories of any such adulterated or misbranded foods or drugs; and provides a penalty therefor.

Section 3 provides: "That the Secretary of the Treasury, the Secretary of Agriculture, and the Secretary of Commerce and Labor shall make uniform rules and regulations for carrying out the provisions of this act, including the collection and examination of specimens of foods and drugs," etc.

Section 4 provides for the examination of foods and drugs, and the giving of notice if found to be adulterated or misbranded.

Section 5 makes it the duty of the district attorney to whom report shall be made of any violation of the act, to cause appropriate pro-

ceedings to be commenced, without delay, for the enforcement of the penalties provided in the act.

Section 6 defines the meaning and inclusion of the terms drug and food.

Section 7 declares that for the purposes of this act an article shall be deemed to be adulterated: "In case of drugs: First. If when a drug is sold under or by a name recognized in the United States Pharmacopœia, or National Formulary, it differs from the standard of strength, quality, or purity, as determined by the test laid down in the United States Pharmacopœia, or National Formulary, official at the time of investigation: Provided that no drug defined in the United States Pharmacopœia, or National Formulary, shall be deemed to be adulterated under this provision if the standard of strength, quality, or purity be plainly stated upon the bottle, box, or other container thereof, although the standard may differ from that determined by the test laid down in the United States Pharmacopœia, or National Formulary.

"Second, if its strength or purity fall below the professed standard or quality under which it is sold." (Other portions of the section relate to confectionery and foods.)

SECTION 8. "That the term 'misbranded,' as used herein, shall apply to all drugs or articles of food, or articles which enter into the composition of food, the package or label of which shall bear any statement, design, or device regarding such article, or the ingredients or substances contained therein, which shall be false or misleading in any particular, and to any food or drug product which is falsely branded as to the State, Territory, or country in which it is manufactured or produced. That for the purposes of this act an article shall also be deemed to be misbranded: 'In case of drugs, first, if it be an imitation of, or offered for sale under the name of, another article. Second, if the contents of the package as originally put up shall have been removed, in whole or in part, and other contents shall have been placed in such a package, or if the package fail to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any substances contained therein." (Remainder of section applies to foods.)

Section 9 relates to guarantees by wholesalers, jobbers, and manufacturers.

Section 10 provides for the seizure and condemnation of adulterated or misbranded foods, drugs, and liquors through proceedings instituted for the purpose, which proceedings "shall conform, as near as may be, to the proceedings in admiralty, except that either party may demand trial by jury of an issue of fact joined in any such case, and all such proceedings shall be at the suit of and in the name of the United States."

Sections 11, 12, and 13 have no possible bearing on the questions involved.

Acting upon the recommendation of the commission of experts the Secretaries of the Treasury, of Agriculture, and of Commerce

and Labor, respectively, adopted certain rules and regulations for carrying out the provision of the foregoing act on October 17, 1906, and published the same.

Regulation 28 was amended to take effect on April 1, 1910. This states the derivatives of the several drugs enumerated in section 8 and names the several preparations containing them respectively. Derivatives of or from and preparations containing acetanilide are enumerated as follows:

"Acetanilide (antifebrine, phenylacetamide).

"Derivatives: Acetphenetidine, citrophen, diacetanilide, lactophenin, methoxy-acetanilide, methylacetanilide, para-iodacetanilide, and phenacetine.

"Preparations containing acetanilide or derivatives: Analgesics, antineuralgics, antirheumatics, cachets, capsules, cold remedies, elixirs, granular effervescing salts, headache powders, mixtures, pain remedies, pills, and tablets."

The regulation concludes as follows: "In declaring the quality or proportion of any of the specified substances the names by which they are designated in the act shall be used, and in declaring the quantity or proportion of the derivatives of any of the specified substances, in addition to the trade name of the derivative, the name of the specified substance shall also be stated, so as to indicate clearly that the product is a derivative of the particular specified substance."

1. A preliminary contention on behalf of the appellants is that the act being remedial and not penal, should be liberally construed. This contention seems to be of little or no practical importance in the present case, as the substantial question presented is one of power rather than construction. Without discussion, therefore, it may be conceded that the act, while it contains penal provisions without which it could not be enforced, was enacted to remedy the great mischief resulting from the unrestricted sale of adulterated drugs and articles of food and ought to be given, where possible, a construction that will effect the general legislative intention.

2. The substantial questions for determination arise upon two propositions that have been submitted in support of the contention of error in the dismissal of the bill on the exceptions stated. The first of these is: That the packages of the drug are misbranded, because the labels fail to recite that acetphenetidin contained therein is a derivative of acetanilide.

It seems clear that this omission is not in express violation of the requirement of section 8 of the act, for the reason that the label states the true name of the drug—acetphenitidine, which,
17 though not one of those specifically named in the section, is a derivative of one of them—acetanilide.

Now, while persons skilled in chemistry and pharmacy would know that acetphenitidine is a derivative of acetanilide, it is certain that the average purchaser and user of drugs would not. For this reason, no doubt, the commission of expert chemists, whose recommendations were adopted by the three secretaries, suggested the regulation requiring the label of a derivative of one of the drugs specified in section 8 to show not only the trade name of the same, but also

the name of the substance of which it is a derivative. It is well settled that where an act of Congress has for its object the raising of revenue, the administration of the affairs committed to an executive department, as of the public lands, and the like, or the execution of the power over commerce, matters of detail looking to the promulgation of regulations for carrying the law into effect, as, for example, providing for the proceedings thereunder, the fixing of standards, brands and labels, or the ascertainment of necessary facts upon which the law may operate, may be expressly delegated to an executive officer. In such instances Congress legislates on the subject as far as is reasonably practicable, and from the recognized necessities of the case is compelled to leave to executive officers the duty of bringing about the result pointed out by the statute. U. S. v. Bailey, 9 Pet., 238; U. S. v. Caha, 152 U. S., 211; In re Kollock, 165 U. S., 526; Field v. Clark, 143 U. S., 470; Union Bridge Co. v. U. S., 204 U. S., 364; St. L. & I. M. Ry. Co. v. Taylor, 210 U. S., 281; Bong v. Campbell Art Co., 214 U. S., 236; see also Coopersville Co-operative Creamery Co. v. Lemon, 163 Fed. R., 145; Prather v. U. S., 9 App. D. C., 82; Kollock v. U. S., 9 App. D. C., 120.

On the other hand, it is equally well settled that the power conferred to make regulations for carrying the law into effect must be exercised within the powers delegated, that is to say, confined to details for regulating the mode of proceeding to carry into effect the law as it has been enacted by Congress. It can not be extended to amending, or adding to the requirements of the act itself. Morrill v. Jones, 106 U. S., 466; U. S. v. Symonds, 120 U. S., 46; U. S. v. Eaton, 144 U. S., 677; Williamson v. U. S., 207 U. S., 425.

The decisions cited mark the general boundary line between the powers that may be delegated to administrative officers and those that may not be. It remains to determine on which side of that line the power claimed in the present case falls.

It must be borne in mind that the Food and Drugs Act does not confer upon executive officers the power to prescribe the forms of brands and labels upon drugs, as was done by the Oleomargarine Act, that was considered in Kollock's case, supra. The only power conferred is that, in section 3, which provides that the three secretaries named, "shall make uniform rules and regulations for the carrying out of the provisions of this act, including the collection and examination of specimens of food and drugs," etc. * * *

Section 8 declares when an article shall be deemed to be misbranded: "First. If it be an imitation of, or offered for sale under the name of, another article." "Second. If (among other things) the package fail to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or any derivative or preparation of any such substances contained therein."

In so far as the regulation designates the several derivatives of the drugs enumerated in section 8, and the preparations containing the same, we are of the opinion that it is within the power conferred in section 3 to make uniform rules and regulations for carrying out the provisions of the act. It was not reasonably practicable for Con-

gress to ascertain and declare these several derivatives and preparations, which might then have existed, much less to anticipate those which might later come into existence and use. Having declared that the quantity or proportion of the several derivatives of the named drugs shall be stated on the labels, the ascertainment of such derivatives was a matter of detail properly confined to the executive officers in carrying out the provisions of the law. The regulation having named acetphenetidine as a derivative of acetanilide, the manufacturer complied therewith to the extent of naming the proportion of said derivative contained in the antikamnia tablets, but did not comply with the requirement of the same that it should also recite that it was, in fact, a derivative of acetanilide. The last requirement was, in our opinion, an amendment of or an addition to the act itself, and therefore beyond the powers of the executive authority. Congress reserved to itself the statement of the contents of the labels and did not require that when a drug was a derivative, merely, the name of the drug from whence derived should also be recited. Had it intended that this should be done, it would have so declared distinctly. In this respect the case is clearly differentiated from In re Kollock, supra, and comes within the rule governing the second class of cases before recited, including U. S. v. Eaton, 144 U. S., 677-688; and Williamson v. U. S., 207 U. S., 425-462. In the case last cited, the question was whether a false oath made in final proof required by a regulation of the Commissioner of the Land Office, constituted perjury. The statute made certain requirements in regard to preliminary proofs and reiterated some of them in the section relating to final proofs, but omitted the one, which by the regulations made by the Commissioner under the power conferred by the act to give effect to its provisions, was required. It was held that the power to adopt rules and regulations for the enforcement of the act could not be construed to warrant one that was in fact an addition to the act.

Since the submission of this case, the Supreme Court of the United States has rendered a decision, the opinion in which, delivered by Mr. Justice Lamar, clearly draws the line between those powers which may be delegated by Congress to an executive officer and those which may not. U. S. v. Grimaud (May 1, 1911). That was an indictment for violating a regulation of the Secretary of Agriculture relating to the use and occupancy of public forest reservations. It was said that in the nature of things it was impracticable for Congress to provide regulations for the various and varying details of the management of the forest reservations, and that it was within its power to authorize the Secretary to make such regulations as would secure the objects of such reservation, namely, to regu-
18 late the use and occupancy and preserve the forests from destruction. Having so done, it declared that "Any violation of the provisions of this act, or such rules and regulations shall be punished as provided in section 5388, R. S., as amended." The violation of such reasonable rules and regulations is "made a crime, not by the Secretary, but by Congress. The statute, not the Secretary, fixes the penalty." It is this feature of the act that differenti-

ated the case from Williamson v. U. S., supra, and other cases cited, which in our opinion furnish the rule of determination for the case at bar. Congress here prescribed what the labels should contain, and conferred no power upon the secretaries to make a regulation adding anything thereto.

3. The second proposition is this in substance: The statement on the label that the drug "contains no acetanilide" is false and misleading, and constitutes misbranding within the meaning of the act. The libel does not expressly charge that acetphenetidine contains acetanilide. If it did, there would be no doubt of the soundness of the proposition, for the exceptions necessarily admit every fact plainly alleged. But it contains no such allegation. It charges that the labels are false and misleading "for the reason that each and all of said labels bear the statement that no acetanilide is contained therein, and that said statement imports and signifies that there is no quantity or proportion of any derivative of acetanilide contained in said drug." It is argued in support of the proposition that acetphenetidine necessarily contains some appreciable quantity or proportion of the latter drug; and it is further argued that this is a matter of common knowledge of which the court may take notice without proof. We can not agree that it is a matter of common knowledge that a chemical derivative necessarily contains, or is of the same nature as, the substance whence it may be derived. It was stated on the argument, without dissent, that very many well-known substances, including acetanilide, are derivatives of benzene or benzol. Some of these derivatives are noxious, others entirely harmless. While, therefore, acetphenetidine is a chemical derivative of acetanilide, and may be derived therefrom in practice, it is in a general sense a derivative of benzene or benzol, and may, for all that we know, be derived therefrom in actual practice for commercial use. When one wishes to ascertain the common meaning or signification of a word, resort is ordinarily had to the accredited dictionaries of the language. Murray's English Dictionary defines a chemical derivative thus: "A compound obtained from another e. g. by partial replacement." The definition of the Standard Dictionary is substantially the same. In the latest edition of Webster's International Dictionary the following definition is given: "A substance so related to another substance by modification or partial substitution as to be regarded as derived from it, even when not obtainable from it in practice." These definitions do not carry us very far. About as far as common knowledge goes is that chemical changes occur in substances through the subtraction or the addition of some particular element. Sometimes the mingling of several substances having chemical affinities, but respectively innocuous, may produce a deadly poison. And sometimes the subtraction of an element from a poisonous substance may produce another that is perfectly harmless. The principles that direct these combinations and control the transformations effected are beyond common knowledge. They can only become known through the special study of the science of chemistry.

Whether, then, the addition or subtraction of elements through which acetphenetidine may, in theory or in practice, be derived from

acetanilide, produces such a chemical change of substance that it may be truly said to contain no acetanilide, or produces a substance which still contains an appreciable quantity or proportion of the same, presents a question of fact which, in our opinion, must be determined on the evidence of witnesses skilled in the science of chemistry.

To authorize the introduction of evidence an issue must be raised in the pleadings.

As before pointed out, the libel does not charge that the statement that the preparation contains no acetanilide is false by reason of the fact that acetphenetidine does contain acetanilide. It carefully confines itself to the allegation that the statement is false because it does not recite that there is no quantity or proportion of any derivative of acetanilide contained therein. This clearly limits the charge of misbranding to the failure to state that acetphenetidine is a derivative of acetanilide. This is but another form of the complaint that the regulation has been violated. It does not raise an issue of fact as to whether acetphenetidine actually contains a perceptible quantity of acetanilide.

In accordance with these conclusions, the judgment will be affirmed. Affirmed.

19 April Term, 1911.

No. 2257.

THE UNITED STATES OF AMERICA, Appellant,
vs.
THE ANTIKAMNIA CHEMICAL COMPANY.

Appeal from the Supreme Court of the District of Columbia.

MONDAY, *May 29th*, A. D. 1911.

This cause came on to be heard on the transcript of the record from the Supreme Court of the District of Columbia and was argued by counsel. On consideration whereof, It is now here ordered, adjudged and decreed by this Court that the decree of the said Supreme Court in this cause be, and the same is hereby, affirmed.

Per MR. CHIEF JUSTICE SHEPARD.
May 29, 1911.

20 In the Court of Appeals of the District of Columbia, April Term, A. D. 1911.

No. 2257.

THE UNITED STATES OF AMERICA, Appellants,
vs.
THE ANTIKAMNIA CHEMICAL COMPANY.

Assignment of Errors.

1. The court erred in holding that the act of June 30, 1906, did not require the labels on the drug in question to bear a statement that the acetphenetidin contained therein is a derivative of acetanilid.

2. The court erred in holding the libel insufficient in point of law.

3. The court erred in holding the libel to be bad in substance.

4. The court erred in sustaining the exceptions of the claimant to the libel.

5. The court erred in dismissing the libel.

6. The court erred in sustaining the third exception to the libel.

7. The court erred in sustaining the fourth exception to the libel.

8. The court erred in sustaining the fifth exception to the libel.

9. The court erred in sustaining the sixth exception to the libel.

10. The court erred in sustaining the ninth exception to the libel.

11. The court erred in holding the charge of misbranding contained in the last paragraph of Paragraph III. of the libel
21 to be insufficient in point of law.

(Endorsed:) No. 2257. The United States of America, Appellant, vs. The Antikamnia Chemical Company. Assignment of Errors. Court of Appeals, District of Columbia. Filed Oct. 3, 1911. Henry W. Hodges, Clerk.

22 No. 2257.

THE UNITED STATES OF AMERICA, Appellant,
vs.
THE ANTIKAMNIA CHEMICAL COMPANY.

TUESDAY, *October 3d*, A. D. 1911.

It is ordered by the Court that an appeal and writ of error to the Supreme Court of the United States in the above entitled cause, prayed by Mr. John Lewis Smith, on behalf of counsel for the appellant, be and the same are hereby allowed.

23 UNITED STATES OF AMERICA, *ss:*

The President of the United States to the Honorable the Justices of the Court of Appeals of the District of Columbia, Greeting:

Because in the record and proceedings, as also in the rendition of the judgment of a plea which is in the said Court of Appeals before you, or some of you, between The United States of America, Appellant, and The Antikamnia Chemical Company, Appellee a manifest error hath happened, to the great damage of the said Appellant as by its complaint appears. We being willing that error, if any hath been, should be duly corrected, and full and speedy justice done to the parties aforesaid in this behalf, do command you, if judgment be therein given, that then under your seal, distinctly and openly, you send the record and proceedings aforesaid, with all things concerning the same, to the Supreme Court of the United States, together with this writ, so that you have the same in the said Supreme Court at Washington, within 30 days from the date hereof, that the record and proceedings aforesaid being inspected, the said Supreme Court may cause further to be done therein to correct that error, what of right, and according to the laws and customs of the United States should be done.

Witness the Honorable Edward D. White, Chief Justice of the United States, the 3d day of October, in the year of our Lord one thousand nine hundred and eleven.

[Seal Court of Appeals, District of Columbia.]

HENRY W. HODGES,
Clerk of the Court of Appeals of the District of Columbia.

Allowed by

——— ———.

24 UNITED STATES OF AMERICA, *ss:*

To The Antikamnia Chemical Company, Greeting:

You are hereby cited and admonished to be and appear at a Supreme Court of the United States, at Washington, within 30 days from the date hereof, pursuant to a writ of error, filed in the Clerk's Office of the Court of Appeals of the District of Columbia, wherein The United States of America is plaintiff in error, and you are defendant in error, to show cause, if any there be, why the judgment rendered against the said plaintiff in error as in the said writ of error mentioned, should not be corrected, and why speedy justice should not be done to the parties in that behalf.

Witness, the Honorable Seth Shepard, Chief Justice of the Court of Appeals of the District of Columbia, this 3d day of October, in the year of our Lord one thousand nine hundred and eleven.

SETH SHEPARD,
Chief Justice of the Court of Appeals of the District of Columbia.

Service accepted.

DANIEL W. BAKER,
Counsel for Antikamnia Chemical Co.

[Endorsed:] Court of Appeals, District of Columbia. Filed Oct. 5, 1911. Henry W. Hodges, clerk.

25 UNITED STATES OF AMERICA, ss:

To The Antikamnia Chemical Company, Greeting:

You are hereby cited and admonished to be and appear at a Supreme Court of the United States, at Washington, within 30 days from the date hereof, pursuant to an order allowing an appeal, filed in the Clerk's Office of the Court of Appeals of the District of Columbia, wherein The United States of America is appellant and you are appellee, to show cause, if any there be, why the decree rendered against the appellant, should not be corrected, and why speedy justice should not be done to the parties in that behalf.

Witness, the Honorable Seth Shepard, Chief Justice of the Court of Appeals of the District of Columbia, this 3d day of October, in the year of our Lord one thousand nine hundred and eleven.

SETH SHEPARD,
Chief Justice of the Court of Appeals of the District of Columbia.

Service accepted.

DANIEL W. BAKER,
Counsel for Antikamnia Chemical Co.

[Endorsed:] Court of Appeals, District of Columbia. Filed Oct. 5, 1911. Henry W. Hodges, clerk.

26 Court of Appeals of the District of Columbia.

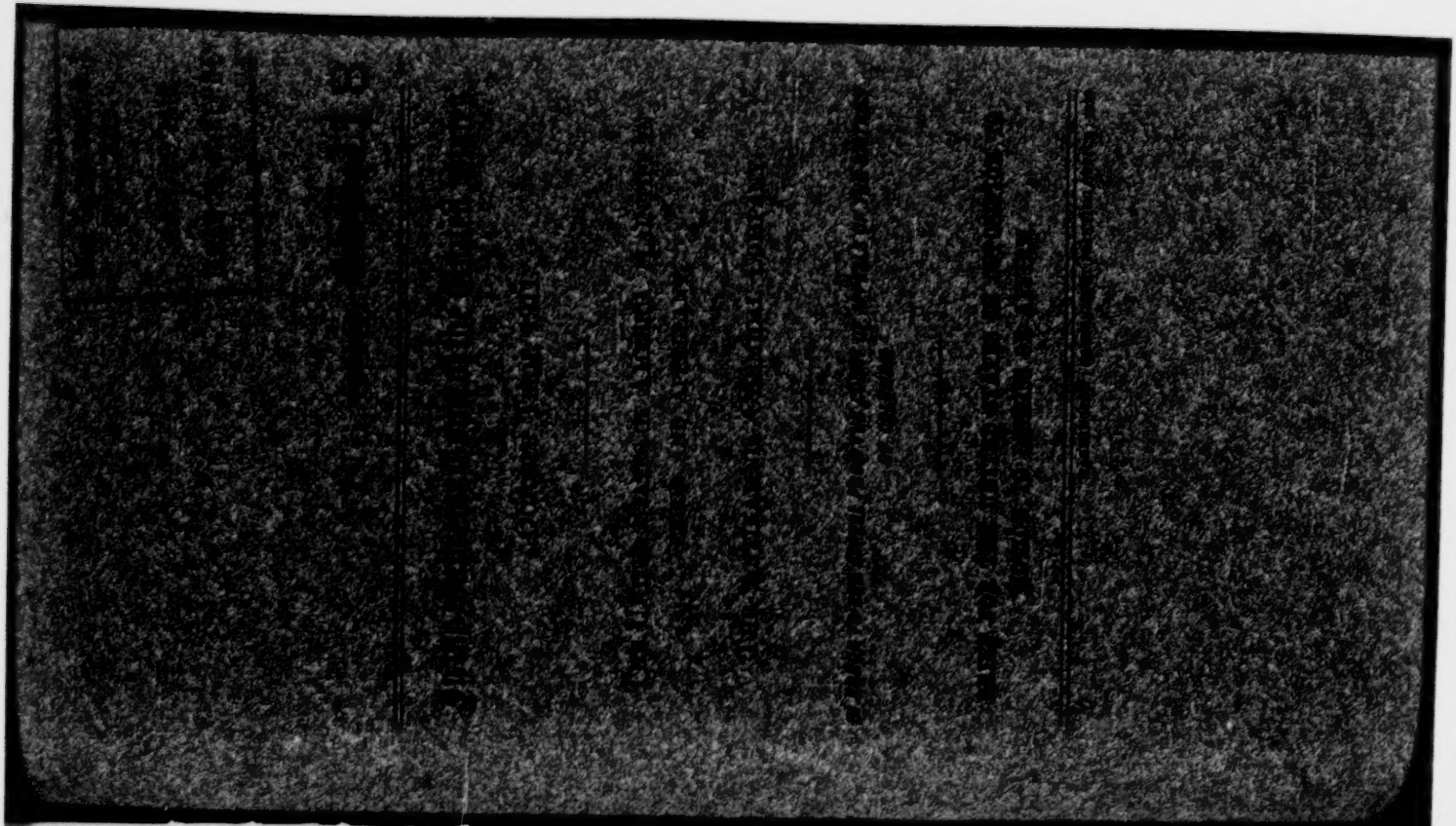
I, Henry W. Hodges, Clerk of the Court of Appeals of the District of Columbia, do hereby certify that the foregoing printed and typewritten pages numbered from 1 to 25 inclusive contain a true copy of the transcript of record and proceedings of said Court of Appeals in the case of The United States of America, Appellant, vs. The Antikamnia Chemical Company, No. 2257, October Term, 1911, as the same remains upon the files and records of said Court of Appeals.

In testimony whereof I hereunto subscribe my name and affix the seal of said Court of Appeals, at the City of Washington, this 7th day of October, A. D. 1911.

[Seal Court of Appeals, District of Columbia.]

HENRY W. HODGES,
Clerk of the Court of Appeals of the District of Columbia.

Endorsed on cover: File No. 22,912. District of Columbia Court of Appeals. Term No. 836. The United States of America, plaintiff in error and appellant, vs. The Antikamnia Chemical Company. Filed October 17th, 1911. File No. 22,912.



In the Supreme Court of the United States.

OCTOBER TERM, 1911.

THE UNITED STATES OF AMERICA, plaintiff in error and appellant,
v.
THE ANTIKAMNIA CHEMICAL COMPANY.
No. 836.

IN ERROR TO AND APPEAL FROM THE COURT OF APPEALS OF THE DISTRICT OF COLUMBIA

BRIEF FOR THE UNITED STATES IN OPPOSITION TO MOTION TO DISMISS OR AFFIRM.

This is a libel filed under the Food and Drugs Act of June 30, 1906, 34 Stat. 768. It is prosecuted for the condemnation of one hundred packages of antikamnia tablets as being misbranded.

These tablets contain acetphenetidin, which is a derivative of acetanilide. The labels upon the packages state the proportion of acetphenetidin contained in the tablets, but do not state that acetphenetidin is a derivative of acetanilide. The labels do state that the tablets contain no acetanilide. (R., 2, 3.)

The libel charges the tablets to be misbranded, because (1) the labels do not state that acetphenetidin is a derivative of acetanilide, and (2) they do

state that the tablets contain no acetanilide, and so are false and misleading as importing that no derivative of acetanilide is contained in the tablets. (R., 3.)

The exceptions to the libel are to the effect that the law does not require the first statement, and that the second is true, and so can not be false or misleading. (R., 6, 7.)

The exceptions were sustained by the Supreme Court of the District of Columbia and the libel dismissed, and this action was affirmed by the Court of Appeals. (R., 8, 21.)

The case is brought to this court by the United States, and the defendant and appellee moves to dismiss the appeal for want of jurisdiction and, failing this, to affirm the judgment on the ground that the appeal is frivolous.

The Food and Drugs Act.

so far as here involved, provides:

> SEC. 3. That the Secretary of the Treasury, the Secretary of Agriculture, and the Secretary of Commerce and Labor shall make uniform rules and regulations for carrying out the provisions of this Act, including the collection and examination of specimens of foods and drugs manufactured or offered for sale in the District of Columbia, or in any Territory of the United States, or which shall be offered for sale in unbroken packages in any State other than that in which

they shall have been respectively manufactured or produced, or which shall be received from any foreign country, or intended for shipment to any foreign country, or which may be submitted for examination by the chief health, food, or drug officer of any State, Territory, or the District of Columbia, or at any domestic or foreign port through which such product is offered for interstate commerce, or for export or import between the United States and any foreign port or country.

Section 6 defines drugs, as follows:

That the term "drug," as used in this Act, shall include all medicines and preparations recognized in the United States Pharmacopœia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals.

Section 8 provides:

That the term "misbranded," as used herein, shall apply to all drugs * * * the package or label of which shall bear any statement, design, or device regarding such article, or the ingredients or substances contained therein which shall be false or misleading in any particular. * * *

That for the purposes of this Act an article shall also be deemed to be misbranded in case of drugs:

* * * * *

Second. If the contents of the package as originally put up shall have been removed, in whole or in part, and other contents shall have been placed in such package, or if the package fail to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any such substances contained therein.

Section 10 provides:

That any article of food, drug, or liquor that is adulterated or misbranded within the meaning of this Act, and is being transported from one State, Territory, District, or insular possession to another for sale, or, having been transported, remains unloaded, unsold, or in original unbroken packages, or if it be sold or offered for sale in the District of Columbia or the Territories, or insular possessions of the United States, or if it be imported from a foreign country for sale, or if it is intended for export to a foreign country, shall be liable to be proceeded against in any district court of the United States within the district where the same is found, and seized for confiscation by a process of libel for condemnation. And if such article is condemned as being adulterated or misbranded, or of a poisonous or deleterious character, within the meaning of this Act, the same shall be disposed of by destruction or sale, as the said court may direct, and the proceeds thereof, if sold, less the legal costs

and charges, shall be paid into the Treasury of the United States, but such goods shall not be sold in any jurisdiction contrary to the provisions of this Act or the laws of that jurisdiction: *Provided, however*, That upon the payment of the costs of such libel proceedings and the execution and delivery of a good and sufficient bond to the effect that such articles shall not be sold or otherwise disposed of contrary to the provisions of this Act, or the laws of any State, Territory, District, or insular possession, the court may by order direct that such articles be delivered to the owner thereof. The proceedings of such libel cases shall conform, as near as may be, to the proceedings in admiralty, except that either party may demand trial by jury of any issue of fact joined in any such case, and all such proceedings shall be at the suit of and in the name of the United States.

Pursuant to the authority conferred by section 3 of the act, the Secretaries named adopted regulation 28, which, so far as here involved, provides (R., 10–12):

* * * * *

(*c*) A drug or food product except in respect of alcohol, is misbranded in case it fails to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, heroin, cocaine, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any such substances contained therein.

* * * * *

(*f*) The following are the principal derivatives and preparations made from the articles which are required to be named upon the label:

* * * * *

Acetanilide (Antifebrine, Phenylacetamide):

Derivatives—Acetphenetidine, citrophen, diacetanilide, lactophenin, methoxy-acetanilide, methylacetanilide, paraiodoacetanilide, and phenacetine.

Preparations containing acetanilide or derivatives—Analgesics, antineuralgics, antirheumatics, cachets, capsules, cold remedies, elixirs, granular effervescing salts, headache powders, mixtures, pain remedies, pills, and tablets.

(*g*) In declaring the quantity or proportion of any of the specified substances the names by which they are designated in the act shall be used, and in declaring the quantity or proportion of derivatives of any of the specified substances, in addition to the trade name of the derivative, the name of the specified substance shall also be stated, so as to indicate clearly that the product is a derivative of the particular specified substance.

I.

The motion to dismiss the appeal.

The Court of Appeals held invalid the regulation requiring the name of the primary substance as well as that of the derivative to be stated on the

label; and there is here not only drawn in question, but so far denied, an authority exercised under the United States.

The case seems to be governed by *United States ex rel. Steinmetz* v. *Allen*, 192 U. S. 543. In that case there was a rule of practice in the Patent Office, rule 41, which provided that two or more independent inventions could not be claimed in one application. The challenge of this rule, it was insisted, did not draw in question the validity of an authority exercised under the United States, but this court said, page 556:

> By section 483 of the Revised Statutes, the Commissioner of Patents, subject to the approval of the Secretary of the Interior, is empowered to establish from time to time regulations not inconsistent with law, for the conduct of proceedings in the Patent Office. The Commissioner of Patents, exercising the power conferred, established, among other rules of practice, rule 41. It thereby became a rule of procedure and constituted, in part, the powers of the primary examiner and Commissioner. In other words, it became an authority to those officers, and, necessarily, an authority "under the United States." Its validity was and is assailed by the plaintiff in error. We think, therefore, we have jurisdiction, and the motion to dismiss is denied.

In the case at bar we have the same situation. The act of Congress provides that the Secretaries

shall make uniform rules and regulations for carrying out the provisions of the act; and the Secretaries, in pursuance of that mandate of the law, have made the regulation in question. Here, as in the *Steinmetz* case, the validity of the rule is challenged.

It was held in the *Steinmetz* case by the Supreme Court of the District and the Court of Appeals that the rule of the Patent Office was valid. This court held it to be invalid. In the case at bar the Supreme Court of the District and the Court of Appeals held the rule to be invalid, and this is the only difference between the cases. But surely the fact that the authority was upheld by the lower courts against the challenge in the one case while the challenge was sustained in the other does not alter the fact that in each case the rule was an authority under the United States and that its validity was drawn in question.

The case at bar is squarely within the rule laid down in *United States* v. *Lynch*, 137 U. S. 280, wherein it is said (p. 285):

> * * * The validity of a statute or the validity of an authority is drawn in question when the existence, or constitutionality, or legality of such statute or authority is denied, and the denial forms the subject of direct inquiry.

That is precisely the case here. The Secretaries have assumed and exercised the authority to make the regulation in question, and the very existence

or legality of the authority thus assumed and exercised by them is denied, and the denial is the subject of direct inquiry, because it is the very basis of the lower court's action.

In *Snow* v. *United States*, 118 U. S. 346, it was said (l. c., 353):

> * * * The authority exercised by the court in the trial and conviction of the plaintiff in error is not such an "authority" as is intended by the act. The validity of the existence of the court, and its jurisdiction over the crime named in the indictments, and over the person of the defendant, are not drawn in question. All that is drawn in question is whether there is or is not error in the administration of the statute.

And so in other cases cited by the appellee where the appeal was dismissed, the question was not as to the validity of the authority, but of regularity of administration under it. Here, however, as in the *Steinmetz* case, the rule or regulation is the authority under which proceedings are pending, and the question is not as to the propriety or regularity of any of the proceedings, but of the validity of the rule or regulation itself.

II.

The motion to affirm.

Section 3, as we have seen, requires that the Secretaries "shall make uniform rules and regulations for carrying out the provisions of this Act."

Pursuant to this the Secretaries have ascertained what are the derivatives in use of the various drugs named in section 8 of the act, and have prescribed that the name of the derivative shall be stated on the label of any package in the contents of which it is found. This is merely determining or ascertaining certain facts and applying to them the plain terms of the law.

The Secretaries provided also that where the derivative was required to be stated the name of the parent or primary substance should also be stated.

It is to be borne in mind that in chemistry the derivative is not necessarily, and, perhaps, not usually, obtained from the specified primary substance. It may be derived from it or it may be independently produced. The designated derivative as made by one process can not be distinguished from that derivative as made by another process. Acetphenetidin may be made from acetanilide or it may not be, but, however made, it is acetphenetidin, and it is accepted as a derivative of acetanilide because of its chemical affinity or relation to that substance. It has the same or similar therapeutic effects; it is a like kind of poison.

With respect to the drugs specifically mentioned in secton 8, Congress had a distinct purpose in mind. Adulteration was not the evil chiefly in view. The use of these drugs at all was the matter under consideration. They are all narcotics or

stimulants of the evil habit-forming kind, and the purpose of the law was to prevent people from being lured into the use of these poisons.

So, if a preparation contained opium, or any other of the specified drugs, the label must say so, and say how much. And in like manner, if the preparation contained the derivative, the label must say so, and say how much. Why was the derivative put upon the same footing with the primary drug? Not because of how it was made by man, but because of what it would do to man if he used it. The law is against selling preparations of these drugs or their derivatives without plainly informing the public by means of the labels just what the noxious stuff is in each case.

The law does not state in what language the label shall speak. So far as concerns the literal terms of the law, they would be satisfied with Sanskrit. The Secretaries, by regulation 17, have provided that the label shall speak English; and it is submitted that this is not an extension or expansion of the law, but a mere administration of it, and a failure to label in English as prescribed by the regulation would be a violation of the law itself.

The law says nothing as to the mechanical features of the label, and its literal terms would be satisfied by a microscopic legend not within the ordinary power of vision to read. The Secretaries by this same regulation have provided that the size of the type used to declare the information required

by the act shall not be smaller than 8-point (brevier) capitals, with the provision, however, that if the size of the package will not permit the use of such type the size of the type may be reduced proportionately.

The right to make such rules, and even the duty to make them, inheres in the act, and, when made, they are a part of the act, for unless the information is given in legible type and in a language intelligible to our people it is not given at all.

Now, the derivatives are by the plain terms of the law held to be as harmful as the primary substances, and the plain purpose of the law is, that the people when they buy a preparation of opium, or its derivatives, shall know that they are buying a preparation of opium, or of a derivative of opium.

And this they will not know unless they are told by the label in plain type and plain English not simply the trade name of the noxious derivative in the preparation, but of what it is a derivative.

The drugs specifically mentioned in the statute are quite generally known, but not so their many derivatives with unpronounceable and unremembrable names. We refer to pages 10 to 12 of the record. Take a few of the simpler cases. The average person is not an expert in chemical terminology, and he would not recognize morphine in dionine or peronine, or opium in codeine, or cocaine in oleate, or chloral hydrate in dormiol, hypnal, or uraline, or acetanilide in acetphenetidin, citrophen, or lacto-

phenin. To state on the label simply the trade name of a derivative, which might be whatsoever the manufacturer pleased, as, for example, para-iodoacetanilide, would be as informing as a Sanskrit label in small print.

Oleate is a derivative of cocaine, but how many people know that fact? The name is not only not suggestive but in itself misleading. The law intends that if a man buys oleate he shall know not simply that it is oleate, but that oleate is a derivative of cocaine. He is not to be lured or tricked into the use of cocaine or its equivalent, for the derivative is, in chemistry and medicine *and in this statute*, essentially an equivalent.

And so the Secretaries provided by amendment of regulation 28, as to the label, that "in declaring the quantity or proportion of derivatives of any of the specified substances, in addition to the trade name of the derivative, the name of the specified substance shall also be stated, *so as to indicate clearly that the product is a derivative of the particular specified substance.*" That is, make the label speak plain English. And this, we submit, does not extend the law, but only applies it.

Now, in the case at bar the labels stated simply the proportion of acetphenetidin contained in the tablets. There was nothing on the label to inform anyone not a chemical expert that the preparation contained a derivative of a drug so dangerous that the law had placed it, with its derivatives, in the

category of subtle and dangerous things; and, more than this, the label stated in terms that the tablets contained no acetanilide or other substances specified in the law—making the label display an absolute safety signal where the law positively required one of warning.

The regulation here involved bears the same relation to the case as that in *United States* v. *Bailey*, 9 Peters 238, and that in *Caha* v. *United States*, 152 U. S. 211. The statute forbids and punishes misbranding. It does not, however, describe what is proper branding, deviation from which constitutes misbranding. It left that as a matter of detail to be determined by the Secretaries. They have said that a proper branding of acetphenetidin requires the statement that it is a derivative of acetanilide. Only so does the branding give the information which the law requires. That the particular acetphenetidin in question was not, so far as concerns the process of manufacture, derived from acetanilide is not to the purpose. It is a derivative in the therapeutic sense. Not to brand it as the regulation prescribes, and beyond that to make the statement that the drug contains no acetanilide when it does contain its equivalent, is to misbrand the article and so to violate the law.

This is not the place for a full argument of the questions involved on their merits. It has been the purpose only to go far enough to show that there

is something serious to be said in support of them and that this appeal is by no means a frivolous one.

Respectfully submitted.

F. W. LEHMANN,
Solicitor General.

JANUARY, 1912.

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No. 118.

In the Supreme Court of the United States.

OCTOBER TERM, 1913.

THE UNITED STATES OF AMERICA, PLAINTIFF IN ERROR AND APPELLANT,

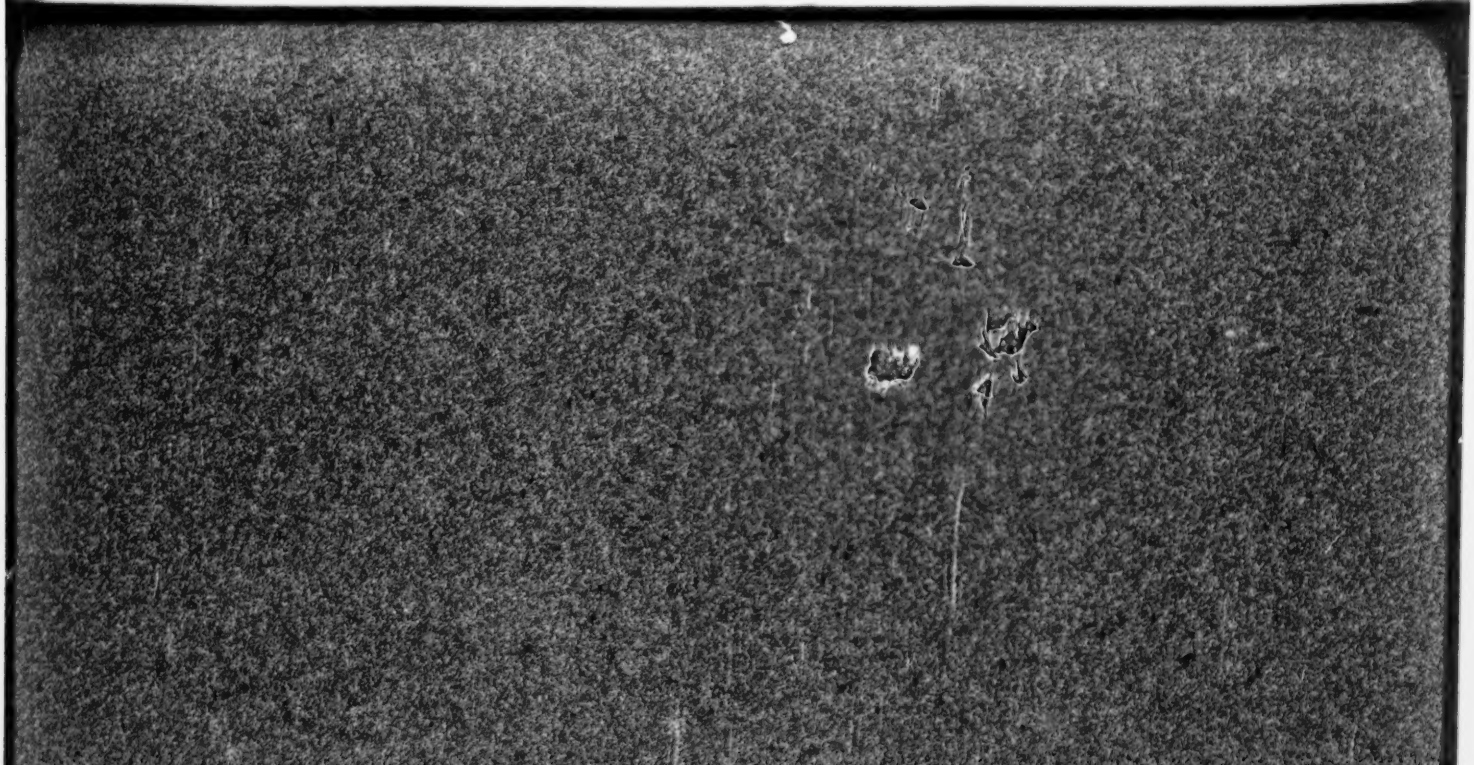
v.

THE ANTIKAMNIA CHEMICAL COMPANY.

IN ERROR TO AND APPEAL FROM THE COURT OF APPEALS OF THE DISTRICT OF COLUMBIA.

BRIEF FOR THE UNITED STATES.

WASHINGTON : GOVERNMENT PRINTING OFFICE : 1913



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IN ERROR TO AND APPEAL FROM THE COURT OF APPEALS OF THE DISTRICT OF COLUMBIA.

BRIEF FOR THE UNITED STATES.

STATEMENT.

This case has already come before this court upon a motion to dismiss or affirm, decision of which was postponed until hearing on the merits. The facts are fully stated in the then Solicitor General's brief in opposition to that motion, filed in January, 1912, and any addition to that statement would be superfluous.

SPECIFICATION OF ERROR.

The Court of Appeals erred in holding that the libel did not charge a misbranding in violation of the Food and Drugs Act, section 8.

BRIEF OF ARGUMENT.

I. This court has jurisdiction.

II. The regulation violated was within the power of the Secretaries to make uniform rules and regulations, and its violation constituted a misbranding within the meaning of the act.

1. The act was designed in part to prevent the use of certain "habit-forming drugs" and their derivatives through ignorance.

(*a*) Debates in Congress may be looked to in order to show the evil which Congress sought to remedy.

(*b*) For the same purpose, this court will recognize well-known scientific facts upon which Congress acted.

2. This purpose would be defeated by permitting the name of the derivative alone to be stated on the label.

(*a*) The average man is unfamiliar with the names of the derivatives.

(*b*) "Derivatives" and "preparations" are classed together, and the names of the latter tell nothing of their contents.

3. Reasonably construed, section 8 of the act requires a statement of the name of the parent substance, and the regulation of the Secretaries to that effect was purely administrative.

(*a*) The act is not penal for purposes of strict construction.

(*b*) Penal statutes should be construed to effectuate the legislative intent.

4. If not, section 8 is incomplete on its face, and the Secretaries were intended and authorized to fill in the outline.

(*a*) The power to make regulations having the force of law may be conferred by general language.

5. The delegation of power to the Secretaries was constitutional.

III. The statements that the tablets contained no acetanilid was misleading within the meaning of section 8.

1. A statement may be misleading under section 8, although literally true.

2. The statement was calculated to suggest that no derivative of acetanilid was contained in the tablets.

3. Section 8 was intended to cover just such deceptions as to identity.

ARGUMENT.

I.

This court has jurisdiction.

The case was brought here under section 233 of the District Code (31 Stat. 1189, 1227), as one in which the validity of an authority exercised under the United States is drawn in question.

The question of jurisdiction was fully argued in the Solicitor General's brief upon the motion to dismiss, and there is little to add to that discussion.

However, the recent case of *Smoot* v. *Heyl*, 227 U. S. 518, seems conclusive of this question. There appellant, a landowner in the District of Columbia, constructed a bay window the wall of which rested upon the boundary line between his and appellee's premises, in reliance upon a building regulation promulgated by the Commissioners of the District permitting the construction of party walls. Appellee sued to enjoin the maintenance of this wall, claiming that it was not a party wall, and that the regulation, if it applied, was unconstitutional, because it deprived him of his property without due process of law. The Supreme Court of the District decreed the removal of the wall, and the Court of Appeals affirmed this decree.

An appeal was taken under section 233 of the District Code. On the jurisdictional question it was said (p. 522):

> This court has jurisdiction. District Code, § 233, Act of March 3, 1901, c. 854, 31 Stat. 1189, 1227; *Steinmetz* v. *Allen*, 192 U. S. 543, 556; *McLean* v. *Denver & Rio Grande R. R. Co.*, 203 U. S. 38, 47, 48. As the appellees challenged the validity of the regulation if it applied to their property as was insisted by the appellant, the case was one in which there was drawn in question

> the validity of an authority exercised under the United States. The question was a substantial one, and was directly presented, its determination being required unless the appellees succeeded upon one of the other issues. To justify a review of the decision under the act governing this appeal it is sufficient if the validity of the authority is drawn in question irrespective of the conclusion reached by the court below.

The case differs from the present one only in that (1) the validity of the authority exercised—*i. e.*, the regulation—was attacked in a civil case, not a criminal action; and (2) the Federal Constitution and not the construction of the statute conferring the power to make regulations was the basis of attack. Neither of these amounts to a legal distinction. The validity of the authority is no less drawn in question in the one case than in the other.

Defendant's contention that the real question presented is not the Secretaries' authority but the proper construction of the statute is therefore beside the mark. It might with equal force have been urged in the *Smoot* case that in reality a mere constitutional question was involved. If sustained, this contention would effectively eliminate this head of appellate jurisdiction.

II.

The regulation violated was within the power of the Secretaries to make uniform rules and regulations, and its violation constituted a misbranding within the meaning of the act.

1. *The purpose of the act.*

In order to read the requirements of section 8 and the authority conferred by section 3 from the viewpoint of those who enacted them, it will be necessary to premise certain data, matters of common knowledge, which were before Congress and entered into its deliberations, regarding the nature and effects of the drugs and derivatives mentioned in section 8.

(*a*) The nature of the evil which the provision in section 8 against misbranded drugs was designed to remedy is plainly shown by a reference to the Congressional Record—a legitimate mode of ascertaining such facts.

> *Jennison* v. *Kirk*, 98 U. S. 453.
>
> *Holy Trinity Church* v. *United States*, 143 U. S. 457.
>
> *American Net and Twine Co.* v. *Worthington*, 141 U. S. 468.
>
> *Binns* v. *United States*, 194 U. S. 486, 495, 496.
>
> *Blake* v. *National Banks*, 23 Wall. 307, 319.

That evil was, in short, the use of dangerous drugs by persons ignorant of their true character—drugs dangerous both by reason of their habit-

forming propensities and because of their immediate deleterious effects. The object was not directly to prevent the sale or transportation of such articles; it was rather to enable the prospective purchaser to know what he was buying, and thus to deal with the vendor of drugs on equal terms and with his eyes open.

The House bill, which was offered as a substitute for the measure originally introduced by Senator Heyburn (S. 88), at first provided that a drug should be deemed misbranded "if it fail to bear a statement on the label of the quantity or proportion of any alcohol therein, or of any opium, cocaine, or other poisonous substance which may be contained therein."

When Mr. Mann introduced this substitute measure in the House he said:

> It is proposed to offer an amendment to this provision (*i. e.*, as to misbranding) which in effect will provide that the * * * amount of alcohol and of opium, morphine, cocaine, heroin, alpha and beta eucaine, acetanilid, and chloral hydrate shall be stated, so that people may be informed who purchase prepared medicines whether they are taking habit-forming drugs or alcoholic compounds. * * * The provision in the House bill requiring the amount of alcohol and of habit-forming drugs to be stated in medicinal preparations is not in the Senate bill at all. (Cong. Rec., vol. 40, pt. 9, pp. 8890, 8891.)

That "habit-forming drugs" were the main object of attack in this amendment is shown by Mr. Mann's explanation of the reasons therefor:

> Then we thought that it would not be fair to require this statement, "or other poisonous substance which may be contained therein," after we had given the matter full reflection, both because no one knows what would be the definition of "or other poisonous substance," and also because there are various poisonous substances, in no way habit-forming drugs, the disclosure of which might require the person manufacturing them to disclose their full formula without any benefit to the public. We propose to offer an amendment, setting forth the names of the articles, so that we will provide that as to all of these medicines there shall be stated the quantity or proportion of morphine, opium, cocaine, heroin, alpha and beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any such substances contained therein; and I have collected, both through my own efforts and through the efforts of the committee, and I may say partly through the efforts of Mr. Samuel Hopkins Adams, of Collier's Weekly, a large number of instances, some of which I ask to put into the Record, showing where deaths have occurred by reason of these products being placed in soothing sirups and in other medicines offered for sale under various descriptions without anything to indicate the contents. There are medicines now upon the

> market advertised in the strongest language which can be found, for the cure of the opium habit, which medicines themselves contain opium enough to give one the opium habit. (*Id.* p. 8892.)

Defendant objected below that there was no evidence that the drugs in question were habit-forming. The court is referred to a memorandum introduced into the Record by Mr. Mann, which we think will be found to supply the needed proof. (Memorandum of "Habit-forming drugs," Cong. Rec., vol. 40, pt. 9, pp. 8905–8909.) We quote a few passages therefrom to show the nature of the information upon which Congress was acting:

> The following "habit-forming" drugs have, within the last year or two, been stated upon good authority to be contained in the following medicines. These statements have been found in various medical journals and board of health reports and Collier's Weekly:
>
> *Acetanilid.*—Orangeine, Antikamnia, Kohler's Powders, Hed-eze, Bromo-Seltzer, Cephalgine, Electric Headache Powders, A. B. C. Headache Powders, Royal Pain Powders, Miniature Headache Powders, Megrimine, Anti-Headache, Dr. Davis's Headache Powders.
>
> * * * * *
>
> *Acetanilid.*—Acetanilid is a most beneficial and useful medicinal remedy, but during the past few years it has been placed in the hands of the laity in so many forms under the guise of headache cures, neuralgia cures,

etc., that at present there are many women who are unable to do their daily work without taking a portion of some compound containing acetanilid, in order to properly do their daily tasks. A brief perusal of the proprietary remedies handled in a wholesale way throughout this country shows that there are over 300 preparations used for this purpose, and it would probably not be far from the truth to say that all of them contain acetanilid. The following are among the most widely used and well-known headache remedies: "Antikamnia," "Bromo Seltzer," "Harper's Brain Food," and "Red Dragon Seltzer."

"Antikamnia" is largely advertised, and there are very few households in the United States that do not know this remedy, and in many cases there are persons who take some of this remedy daily. The chief constituent is acetanilid. (*Id.* 8905.)

* * * * *

NEW ORLEANS, LA., *November 27, 1905.*

DEAR SIR: It is with great thankfulness that I at last see a ray of enlightenment going to the public about patents. As a druggist in a humble way, I have been trying to educate people in my immediate neighborhood on the proper way of medication via the physician.

I think acetanilid in its various forms more dangerous even than opium, inasmuch as the people have an inkling of the fact that cough sirups, soothing sirups, and patents in that category contain a certain amount of

opium or morphine, but with headache and antineuralgic preparations no such knowledge is as yet extant.

I would call your attention to the fact that Mr. A. Heiman, an immediate neighbor of mine at that time, very nearly died of a dose of two antikamnia tablets taken fifteen or twenty minutes apart, containing 10 grams in all of this compound. If immediate medical help was not available no doubt the makers of this preparation would have been guilty of another murder. I do not see for the life of me why a law could not be passed prohibiting both the manufacture and sale of such nostrums.

Yours truly,

GEO. A. THOMAS.

(*Id.* 8907–8909.)

Equally interesting "testimonials" regarding the use of other acetanilid preparations (such as Bromo Seltzer, Bromo Quinine, and other so-called headache powders) appear on page 8908.

It was subsequently stated, in debate, that (*id.* 8998)—

> The general purpose of this bill is to protect the public health, and it is to secure honesty in trade and to enable people to know just exactly what they get.

See also Cong. Rec., vol. 40, pt. 9, pp. 8987, 9070–9072; *id.* pt. 10, pp. 9073–9075.

The above passages at least establish that the drugs mentioned were represented to Congress as habit-forming; that the derivatives were considered

quite as harmful and as much to be guarded against as the parent substances; and, more particularly, that the dangers attending the use of the preparation manufactured by the defendant were specifically brought to the attention of Congress. The technical distinction between the parent drugs and their derivatives was evidently either not called to the attention of Congress or was disregarded as immaterial for legislative purposes. It was the evil *effects* of certain drugs, sold as harmless or beneficial, at which the amendment was aimed—not at any particular chemical formula.

(*b*) But that a derivative of the substances named frequently has the same noxious effects as the parent substance is a fact capable of demonstration, and one which this court will recognize.

In the court below defendants attacked the propriety of the court's taking judicial notice of scientific facts which, it was asserted, were not matters of common knowledge, although admittedly obtainable from any textbook or encyclopedia upon the subject. That contention may be renewed here: it hardly seems worthy of serious discussion. That this court will not take cognizance of facts necessary to enable it to read a statute with an understanding eye and in the light of congressional intent, but will deliberately close its mind to such knowledge because not possessed by the man in the street, is a proposition which, when stated, refutes itself. If this were an accepted canon of statutory construction it would be vain for the legislature to

inform itself with a view to intelligent legislation; for the court, lacking the information upon which the statute was founded, could not but pervert its meaning.

Such in substance is the attitude taken by this court in *Austin* v. *Tennessee*, 179 U. S. 343, 348, and *Muller* v. *Oregon*, 208 U. S. 412, 420. In the latter case the court said, in regard to statutes and reports of commissions dealing with hours of labor for women:

> The legislation and opinions referred to in the margin may not be, technically speaking, authorities, * * * yet they are significant of a widespread belief that woman's physical structure, and the functions she performs in consequence thereof, justify special legislation restricting or qualifying the conditions under which she should be permitted to toil. * * * when a question of fact is debated and debatable, and the extent to which a constitutional limitation goes is affected by the truth in respect to that fact, a widespread and long continued belief concerning it is worthy of consideration.

Surely as liberal a practice should obtain in construing this statute. The case at bar, however, is stronger than those above cited, since the matter here is not one of opinion but of scientific fact. The case, therefore, comes within the reason of the rule that dictionaries and encyclopedias may be looked to for the *definition* of words in a statute, for definition, to be complete, should include the quali-

ties of the thing or things defined—here acetanilid and its derivative acetphenetidin. Such authorities were availed of to determine the properties of oleomargarine in *Schollenberger* v. *Pennsylvania*, 171 U. S. 1, 9–12.

We will not inflict upon this court a dissertation upon the similarity in physiological action between all the drugs mentioned in section 8 and their derivatives, but shall confine ourselves to the drugs with which this case is immediately concerned, *i. e.*, acetanilid and its derivative, acetphenetidin. For the purpose of this comparison we quote from leading medical textbooks:

Culbreth, Materia Medica and Pharmacology, 858, 859:

> *Poisoning* [by acetanilide].—Have sweating, depression, slow breathing, irregular pulse, collapse, vomiting, cyanosis, prostration, death. Empty stomach.
>
> *Poisoning* [by acetphenetidin].—Excessive quantity may produce vomiting, sweating, feeble and rapid pulse, collapse; treat as for acetanilide * * *.

Tyrode, Pharmacology, 108:

> Other aniline derivatives as phenacetine [acetphenetidin] * * * have practically the same action as acetanilid.

C. R. Marshall, Materia Medica, 250–251:

> The following three compounds are mainly analgesic and antipyretic. The first two are closely similar in chemical constitution. 1. Acetanilide. 2. Phenacetine. 3. * * * Also, it (acetphenetidine) has a

similar action to acetanilide, relieving pain if present and reducing fever * * *.

White, Materia Medica and Therapeutics, 5th Ed., 1901, 321, 324:

> Acetanilide occasionally produces in man collapse, cyanosis, very slow respiration, a feeble and irregular pulse, vomiting, profuse sweating, and profound prostration. This drug [acetphenetidine] sometimes produces severe vomiting, sweating, feeble and rapid pulse, and collapse.

Wood, Therapeutics, 612:

> The symptoms of acute poisoning by antifebrin (acetanilide) are vomiting, muscular weakness, cyanosis, coldness of the extremities, subnormal temperature, profuse sweating, disturbances of respiration, fixed dilated pupils, rapid irregular heart action, ending in collapse and cardiac death. * * * The urine may be dark. * * * Leucocytosis with nucleation of the red-blood corpuscles has been noted. The therapeutic dose of phenacetine (acetphenetidine) produces no symptoms, but the toxic dose is said to cause violent vomiting, great cyanosis, chocolate-colored urine, yellow discoloration of the body, leucocytosis, and death.

Cushny, Pharmacology, 5th Ed., 1910, 425–427, 428:

> Antifebrine—or acetanilide—is not entirely devoid of this poisonous action (dangerous collapse and destruction of the blood cells). Large doses of acetanilide tend to produce collapse. In severe cases

> the skin is cold and covered by a clammy perspiration; the heart is weak, irregular and sometimes fluttering, the temperature may be abnormal and the pupils are slightly dilated. * * * The weakness of the heart is the chief source of anxiety and the total failure of the circulation seems to be the cause of death.
>
> Phenacetine is much less poisonous than the foregoing, but in large quantities produces almost identical effect—somnolence followed by convulsions, cyanosis and collapse symptoms, first rapid, then slow respiration and heart.

These data merely serve to reinforce the citations from the Congressional Record as showing that Congress knew what it was about when it classed together the specified drugs and their derivatives.

Defendant quoted statistics below to show that acetphenetidin is decidedly less harmful in its physiological effects than acetanilid. This may be safely conceded, for it does not even tend to prove that Congress did not consider the derivative sufficiently injurious to be included with the parent substance. One of the very authorities cited by defendant stated that both the drugs were dangerous. In short, there is no substantial dispute between defendants and ourselves upon this question of fact—an additional reason why this court should take cognizance of the matter.

There is nothing anywhere to suggest that Congress intended the makers of proprietary medicines to find a refuge from public knowledge in the use

of a derivative instead of its parent substance. Textbooks, the debates, the language of the act, and common sense alike demand the opposite conclusion.

2. *The effect of permitting the name of the derivative alone to be stated.*

(*a*) While the identity of effect between the drugs particularly mentioned and their derivatives thus appears to be well known to pharmacologists and the medical profession, it is obviously a matter about which the general public knows little or nothing. This can hardly be denied by defendant in view of his contention that the fact is of so recondite a nature that even this court may not recognize its existence.

Still less could the average man be expected to know, from the name of the derivative, the substance from which it is derived. On pages 10–12 of the record the court will find the derivatives of the specified substances as set forth by the Bureau of Chemistry. Aside from those derivatives whose names contain the names of the parent substances—such as apomorphine, chloralamide, diacetanilide—who but an expert would suspect the source of a majority of these? A label bearing a statement, "Contains one-tenth ounce of peronine," would be absolutely uninforming to the average person; he would never suspect, much less have reason to know, that he was taking a derivative of morphine.

The names of most of the specified substances are familiar to nearly everyone, and their effects are equally well known. Those names would afford some real information to the purchaser. But if all that section 8 requires on a label is the name of the derivative, it is almost a dead letter so far as substantial protection to the consumer is concerned.

(*b*) But when we come to the "preparations" included in section 8 the fatal result of this construction is even more apparent. The section says, "the quantity or proportion of * * * any derivative or preparation of any such substances contained therein." The words "derivative" and "preparation" must be construed alike, so that if only the name of a derivative need be stated, no more is required of a preparation. As a glance at the record (10–12) will show, however, the names of many of the preparations would not indicate even to an expert chemist the parent substance. For example, the term "elixir" is used to describe preparations of morphine, opium, cocaine, chloroform, chloral hydrate, or alcohol; the words "tincture," "sirup," "tablet," "pill," "solution," have a like scope. In short, any fancy trade name may be adopted to describe a preparation. To say that the use of this nondescript designation is all section 8 requires is reducing the statute to an absurdity. Yet such is the conclusion to which defendant's logic would drive us.

Indeed, it appears from the debates that this particular danger was presented to Congress and sup-

posedly guarded against. The amendment to section 8 as originally presented contained an exception in favor of articles described in the United States Pharmacopœia or National Formulary and prescriptions of a regular licensed physician. This was explained by Mr. Mann as follows:

> I inserted in the Record of yesterday a large number of cases, partly of deaths caused by opium in medicine and partly of habit formed by the use of medicine where the person had no knowledge that opium, morphine, or cocaine was included in the medicine. I think it is only fair to the public that all of these substances shall be made known in these remedies. We do not provide that they shall be made known in the pharmacopœial remedies, because they are all published and fully known to the trade, and it is only the trade which makes use of these pharmacopœial remedies.
>
> Mr. BRICK. As I understand the gentleman from Illinois, this amendment would allow a proprietary medicine to be made from the Pharmacopœia and from the National Formulary, and that when they are so made they need not be published on the label, even though they contain opium or anything else of the character mentioned in this amendment. Is that true?
>
> Mr. MANN. That is true, Mr. Chairman, and it is also true that it can only be sold under the name in which it appears in the Pharmacopœia, and can not be sold as patent medicines are often now sold, under high-

sounding names, tending to make the people believe that there are substances in them which will cure the disease, when it is pure fancy. We do not want to interfere with the sale of proprietary pharmacopœial remedies under their own proper names. That is all. (Cong. Rec., vol. 40, pt. 9, p. 8996.)

The danger in this exemption was suggested in debate, however:

Mr. UNDERWOOD. Mr. Chairman, I think that the present section of the bill that the House is considering is the most important section of the whole bill. There is nothing that the people of the United States need protection against more than they do the poisons in proprietary medicines. Now, I think the gentleman from Illinois, in offering his amendment, has weakened his bill. I think it is leaving the door wide open to deceive the people and allow the people of the United States to be sold poisonous drugs. Now, as the matter has been illustrated to me, and as I understand it, it is simply this: That if a woman goes to a drug store to get medicine for her child and the druggist offers to sell her, after the passage of this bill, Mrs. Winslow's soothing sirup that has got opium in it, he would have to paste across that bottle a label stating that there is opium in that bottle, and she will refuse to buy it because she will not give the child opium, but the druggist will turn around and say, "Here is paregoric, which is just as good." Paregoric is one of those formulas that he can

> sell that is made up by the National Formulary.
>
> Under the terms of the amendment of the gentleman from Illinois, although paregoric has opium in it, the very substance she does not want to give to her child, yet under the terms of this amendment there will be no guard against that; there will be nothing on the bottle to warn her that if she gives the child paregoric she will be giving it opium, and I say this amendment ought to be voted down and the door closed to any deception of that kind. (*Id.* 8998–8999.)

Paregoric, according to the Bureau of Chemistry (R. 11), is a preparation containing opium.

Mr. Underwood's view apparently prevailed; for as finally enacted the bill was without this exemption, which had been struck out in conference. (Cong. Rec., vol. 40, pt. 10, p. 9737.) That this omission was designed to make the bill "the most stringent provision upon this subject which has ever been adopted by any legislative body" is shown by Mr. Mann's speech in presenting the conference report. (*Id.* 9737, 9740.)

3. *A reasonable construction of section 8 therefore requires that the name of the specified substance as well as of its derivative be stated; and the regulation to that effect was purely administrative.*

As has been shown, a construction of section 8 which does not require such a statement leads to

consequences which were not conceivably within the intention of Congress.

If the section is to be construed as narrowly as defendants would have it, however, it can by the exercise of a little ingenuity be even further distorted from the end which Congress had in view. For example, it might be urged that the section merely requires a statement on the label of the *quantity* or *proportion* of alcohol, opium, cocaine, etc., used, and not of their *names*, as set forth in the section. Thus a mind fired with the desire to pervert might argue somewhat plausibly that a label stating "This package contains one-half ounce of a substance named in the pure food and drugs act, section 8," was a literal compliance with the section.

But the plain purpose of Congress is not to be so readily frustrated. The three Secretaries, when they provided in Regulation 28, subsection (*g*), that "in declaring the quantity or proportion of any of the specified substances the names by which they are designated in the act shall be used" (R. 12), merely expressed a requirement which was already within the reasonable intendment of section 8.

In all reason and good sense, then, the remainder of subsection (*g*), that—

> in declaring the quantity or proportion of derivatives of any of the specified substances, in addition to the trade name of the derivative, the name of the specified sub-

> stance shall also be stated, so as to indicate clearly that the product is a derivative of the particular specified substance (R. 12),

is no more than section 8 standing alone should be held to require.

If this be so, the only function of the regulation was to explain and elucidate that which was to be fairly implied from the act. Looked at in this light, it was purely an administrative order and well within the scope of the Secretaries' power. It may have been superfluous; it at least was not *ultra vires*, and defendants have no cause to complain if it simply made more certain a thing which the act already required.

Another consideration tends to the same conclusion. Heroin and chloroform are among the drugs specifically mentioned in section 8. Heroin is a derivative of morphine, and chloroform a derivative of chloral hydrate. These two derivatives are so well known to the public at large that it was evidently believed the use of their names without that of the parent substances would afford the desired information. This is significant of the purpose of section 8; for if only the names of derivatives were required on the label, the mention of heroin and chloroform would be wholly superfluous.

(*a*) It will be objected, however, that the act being penal must be strictly construed, and that a strict construction can not be held to require a statement of the parent substance on the label.

The mere fact that the Food and Drugs Act contains penal provisions does not require a strict construction of its provisions in defendant's favor. This has been frequently held with regard to revenue laws, which, it is said, are "to be regarded as merely remedial in their character and intended to prevent fraud, suppress public wrong, and promote the public good."

Cliquot's Champagne, 3 Wall. 114, 145.
Taylor v. *United States*, 3 How. 197, 210.
United States v. *Hodson*, 10 Wall. 395, 406.
Smythe v. *Fiske*, 23 Wall. 374.
United States v. *Stowell*, 133 U. S. 1, 12.

A statute even more closely analogous is the Interstate Commerce Act. That act contains many and severe penal provisions. Nevertheless, in the case of *New York, New Haven &c. Railroad* v. *Interstate Commerce Com.*, 200 U. S. 361, 391, this court said:

> It cannot be challenged that the great purpose of the act to regulate commerce, whilst seeking to prevent unjust and unreasonable rates, was to secure equality of rates as to all and to destroy favoritism, these last being accomplished by requiring the publication of tariffs and by prohibiting secret departures from such tariffs, and forbidding rebates, preferences and all other forms of undue discrimination. To this extent and for these purposes the statute was remedial and is, therefore, entitled to receive that in-

terpretation which reasonably accomplishes the great public purpose which it was enacted to subserve.

Proceedings for the seizure and detention of property under section 10 of the Food and Drugs Act are entirely distinct and separate from the penal provisions of section 2, *Hipolite Egg Co.* v. *United States*, 220 U. S. 45; *United States* v. *Five Boxes of Asafatida*, 181 Fed. 561, and, aside from the fact of seizure by process *in rem*, are to be regarded as civil actions at common law. *443 Cans of Egg Product*, 226 U. S. 172.

(*b*) Were it conceded that the strict construction appropriate to penal statutes should be adopted, it would not alter the plain meaning of section 8—that the label must state the nature of the drugs beneath it in terms intelligible to the average mind. For even penal statutes are to be construed to carry out so far as possible the legislative intent, and not by a blind adherence to particular words. *United States* v. *Lacher*, 134 U. S. 624; *United States* v. *Harris*, 177 U. S. 305; *Northern Securities Co.* v. *United States*, 193 U. S. 197, 358. This much indeed was conceded by defendants below. As was pointed out by Solicitor General Lehmann in his brief upon the motion to dismiss or affirm (to which the court is referred for an able discussion of the merits of this controversy), section 8 does not in terms require that the label be printed in English or in type large enough to be read by the naked eye. A

label printed in Sanskrit or Chinese, and with microscopic characters, would therefore constitute a *literal* compliance with the section. But can it be seriously urged that a label of that sort would satisfy the intent of Congress? It is quite as reasonable, we submit, to infer that the source of the derivative or preparation should be named in the label as that the label speak English or use decipherable print. For the aim of the section is that certain information shall be conveyed to the purchaser; and these requirements are equally essential to that end.

4. *The only alternative: that section 8 was left incomplete and the Secretaries were intended to fill in the outline.*

If section 8 has not the meaning suggested—if the use of plain type, the English language, and printing the name of the parent substance as well as of the derivative are not to be implied from its language—there is only one reasonable inference open. Congress, in directing the three Secretaries by section 3 to make uniform rules and regulations for enforcing the act, intended to invest them with power to prescribe matters of detail left untouched by the language of section 8 and yet essential to its effectual enforcement. For otherwise it must be concluded that Congress did a vain thing when it enacted section 8, since it left its provisions practically useless for remedial purposes; and that is a conclusion which this court will go far to avoid.

There is a strong presumption against that construction of a statute which virtually nullifies it and defeats its object. *United States* v. *Hartwell*, 6 Wall. 385, 396. The language of this court in *Pickett* v. *United States*, 216 U. S. 456, 461, is here appropriate.

> * * * A construction which might result in such deplorable consequences should not be adopted if a more sensible meaning can be reasonably given. The reason of the law, as indicated by its general terms, should prevail over its letter, when the plain purpose of the act will be defeated by strict adherence to its verbiage. Applications of this general rule are shown in *Holy Trinity Church* v. *United States*, 143 U. S. 457; *Lau Ow Bew* v. *United States*, 144 U. S. 47, 59; *United States* v. *Corbett*, 215 U. S. 233, decided at this term.

(*a*) The authority given by section 3 is exceedingly general. Power to "make uniform rules and regulations for the enforcement of this act" seems in terms broad enough to cover the regulations before us, without which (as we have seen) the effective enforcement of section 8 would be out of the question.

That such was the effect of section 3 seems to have been assumed by Congress. We quote again from the Congressional Record:

> Mr. GILBERT of Kentucky. From the reading of this bill—not carefully having read it—it seems to me that a man can not tell

whether he is violating the law or not by reading the bill, and should have to wait until some rule or regulation has been established by the Department fixing the ingredients and component parts, so that a citizen may know when he is violating the law or not.

Mr. MANN. I will say to my friend that the man who wants to get near the dividing line may have to wait for a ruling of the Department when the question arises as to whether an article is deleterious to health or not, and it may require not only a ruling of the Department, but a ruling of the courts before it can be ascertained. But the man who wants to sell good, pure food or drink to the people of the United States can do it without fear of trouble under this bill. [Applause.]

Mr. GILBERT of Kentucky. It is a very nice and very proper sentiment, but——

Mr. MANN. That is the fact.

Mr. GILBERT of Kentucky. Of course it is, but the legislation is aimed at the man who does not want to sell sound and wholesome foods and drinks. When we come to prosecute that man we prosecute him for the violation of a rule issued by the Department, rather than prosecute him for a violation of the terms of this bill, and that being true, is there any trouble in the enforcement of the law on that line?

Mr. MANN. I do not think there is any trouble in the enforcement of the law on that

> line. The same matter of legislation is being enforced in the various States all over the United States. And, permit me to say to my friend from Kentucky, that the man who violates the law does not merely violate a rule, he violates an act of Congress, which defines what are adulterations and what are misbrandings, and the rule, like the fixing of the rate on a railroad, is simply carrying out a mandate of Congress, the law of Congress. (Vol. 40, pt. 9, 8895.)

The authorities support this construction of section 3.

In *United States* v. *Bailey*, 9 Pet. 238, the defendant was convicted of perjury for swearing falsely in support of a claim against the United States. It was proved that he had made false oath before a justice of the peace, under a regulation by the Secretary of the Treasury that affidavits made before such officers would be received in evidence upon the claims in question. No statute authorized the administration of the oath, nor expressly empowered the Secretary to make such a regulation. The claims act, however, did provide "that the Secretary of the Treasury be, and he is hereby, directed and required to adjust and settle these claims." This court held, through Mr. Justice Story (p. 253)—

> * * * that the Secretary of the Treasury did, by implication, possess the power to make such a regulation, and to allow such affidavits in proof of claims, under the act of

> 1832. * * * It was incident to his duty and authority, in settling claims, under that act * * *. It is a general principle of law, in the construction of all powers of this sort, that where the end is required, the appropriate means are given.

In *Caha* v. *United States*, 152 U. S. 211, a conviction for perjury under Revised Statutes section 5392 was sustained, where the oath was taken in a contest in a local land office in respect to the validity of a homestead entry, under a regulation of the Commissioner of the General Land Office. The latter official was authorized to enforce and execute by appropriate regulations the provisions of the Revised Statutes for the disposition of the public lands. R. S., secs. 453, 2478. The local land officers were authorized to administer any oath required by law or by the instructions of the General Land Office in connection with public-land entries. R. S., sec. 2246. It was held that this was sufficient to authorize the regulation under which the oath was taken, and that said oath was taken "before a competent tribunal" and "in a case in which a law of the United States authorized an oath to be administered" within the meaning of Revised Statutes section 5392.

In *West* v. *Hitchcock*, 205 U. S. 80, a treaty agreement provided that there should be allotted to each member of a certain Indian tribe, both native and adopted, 160 acres of land, title to pass when the allotments were selected and approved by

the Secretary of the Interior. (28 Stat. 876.) A regulation of the Interior Department required that adoption into the tribe must be approved by the Indian Office in order to entitle the adopted member to his allotment under this agreement. This regulation was held to be authorized under section 463 of the Revised Statutes, which provides that—

> The Commissioner of Indian Affairs shall, under the direction of the Secretary of the Interior, * * * have the management of all Indian Affairs, and of all matters arising out of Indian relations.

Mr. Justice Holmes, speaking for the court, said:

> We are disposed to think that authority was conferred by the general words of the statutes (p. 85).

Coopersville Cooperative Creamery Co. v. *Lemon* (C. C. A., 6th C.), 163 Fed. 145,[1] is strictly in point. In that case the plaintiff company was taxed under the act imposing a tax upon the manufacture of adulterated butter (32 Stat. 193). The definition of such butter in section 4 of that act contains the provision:

> * * * any butter in the manufacture or manipulation of which any process or material is used with intent or effect of causing the absorption of abnormal quantities of water, milk, or cream.

[1] *U. S.* v. *11,150 Pounds of Butter* (C. C. A., 8th C.), 195 Fed. 657, *contra*.

Section 20 of the Oleomargarine Act, 24 Stat. 209, 212, incorporated by reference into the later act, provides:

> That the Commissioner of Internal Revenue, with the approval of the Secretary of the Treasury, may make all needful regulations for carrying into effect this act.

Under the authority thus conferred the Commissioner of Internal Revenue promulgated a regulation that butter containing 16 per cent. or more of water, milk or cream should be classed as adulterated butter under the act. This regulation was held to be authorized by section 20 and to be conclusive upon the manufacturer. The court, by Judge (now Mr. Justice) Lurton, said (p. 150):

> * * * While it must be conceded that none of the provisions of the butter act, nor of the general law, in express terms confer authority to determine the per cent. of moisture in dairy butter which shall constitute adulterated or taxable butter, yet it is not easy to escape the conclusion, in view of the general character of the law and of the broad language in which the power to make needful rules to carry the law into execution is conferred, that there is an implied power to determine the fact as to what is an undue, unusual, or, in the words of the act, an "abnormal," incorporation of moisture. An express power to make departmental regulations involving the determination of facts upon which the operation of a law is made to depend is not essential. That which is plainly implied is as much the

> law as that which is expressed in plain terms. For the practical operation of the law it was deemed necessary that the department charged with its execution should have authority to make regulations not inconsistent with law, and this power was accordingly conferred in general terms. The regulation in question is reasonable, is not inconsistent with law, and we see no sufficient ground for saying that it is not within the fair scope and purview of the authority conferred.

See also *Roughton* v. *Knight*, 219 U. S. 537, 546.

An authorization no more explicit than that in section 3 of the Food and Drugs Act, therefore, may well confer the power to make regulations which have the force of law. Indeed, in the *Bailey* and *Hitchcock* cases the administrative officer was not expressly authorized to make any regulations whatsoever; his power was implied from his general control of the subject matter and the necessities of the case. Here these implications are equally cogent, and in addition we have the express direction to the three Secretaries to make regulations for carrying out the provisions of the act. This provision, read in conjunction with the incomplete requirements of section 8, was probably designed to enable the Secretaries to fill in the gaps left by Congress in that section, with regulations carrying out in detail the general legislative purpose as declared therein.

If Congress had merely meant to give the three Secretaries power to prescribe regulations for de-

partmental officers and employees and rules of departmental procedure, section 3 was unnecessary. Such regulations were already authorized by section 161 of the Revised Statutes. In this connection it is significant that the Secretary of Commerce and Labor is one of the officials charged with making the rules and regulations, although no officer or employee of the Department of Commerce and Labor was in any way charged with the execution of the law. The obvious purpose of section 3 was to create a board which should prescribe the numerous details necessarily left untouched by Congress and yet essential to the due operation of the statute.

The regulation before us does not seek to add anything to the law. The act requires acetanilid and its derivatives to be declared upon the label. The regulation requires merely a certain *manner* of declaring the derivatives. It states how the requisite information shall be given. Surely, this is a regulation for "carrying out the provisions" of the act. As this court said in a strikingly similar situation:

> * * * the criminal offence is fully and completely defined by the act and the designation by the Commissioner of the particular marks and brands to be used was a mere matter of detail. The regulation was in execution of, or supplementary to, but not in conflict with, the law itself. [*In re Kollock*, 165 U. S. 526, 533.]

Or again, in the language of *Buttfield* v. *Stranahan*, 192 U. S. 470, 496:

> * * * This, in effect, was the fixing of a primary standard, and devolved upon the Secretary of the Treasury the mere executive duty to effectuate the legislative policy declared in the statute.

In this respect the case differs from those cases cited by defendant and the court below upon this point. Of these, *United States* v. *Eaton*, 144 U. S. 677, perhaps comes nearest the present situation. There, section 20 of the act taxing oleomargarine (24 Stat. 209) authorized the Commissioner of Internal Revenue, with the approval of the Secretary of the Treasury, to "make all needful regulations for the carrying into effect of this act." The Commissioner made a regulation, with the Secretary's approval, requiring *wholesale dealers* in oleomargarine to keep a book showing their receipts and sales of oleomargarine. Section 5 of the act declared *manufacturers* should keep such books as the Commissioner should require, but imposed no penalty for its violation. A violation of the regulation by a wholesale dealer was held not to come under section 18 of the act, which imposed a $1,000 penalty on any manufacturer or dealer who should "knowingly or willfully neglect or refuse to do, or cause to be done, any of the things required by law in the carrying on or conducting of his business." It was conceded that the regulation might have been a

proper one to be made under section 20; but Congress, it was thought, did not intend by that section to authorize the making of a regulation whose violation would be a criminal offense (pp. 686–687).

In the instant case, however, if the regulation was a proper one to be made, its violation must have constituted misbranding under section 8, since its only purpose was to define more fully the meaning of the term "misbranded." Besides, the specific provision in the oleomargarine statute requiring manufacturers to keep books but imposing no penalty quite excluded the inference that wholesale dealers could be required to keep them under pain of a thousand dollar penalty; nor did the general purpose of the act require so drastic a construction. But in the present case, as we have seen, the denial of this power to the Secretaries would effectually hamstring section 8 of the act.

The other cases cited below may be readily disposed of. In *Morrill* v. *Jones*, 106 U. S. 466, the statute (R. S. sec. 2505) provided that—

> Animals, alive, specially imported for breeding purposes from beyond the seas, shall be admitted free [of duty], upon proof thereof satisfactory to the Secretary of the Treasury, and under such regulations as he may prescribe.

It was held that a regulation providing that before a collector admit such animals free he must "be satisfied that the animals are of superior stock,

adapted to improving the breeds in the United States," was not authorized by section 2505. The court said (p. 467):

> * * * This is manifestly an attempt to put into the body of the statute a limitation which Congress did not think it necessary to prescribe. Congress was willing to admit duty free all animals specially imported for breeding purposes; the Secretary thought this privilege should be confined to such animals as were adapted to the improvement of breeds already in the United States. In our opinion, the object of the Secretary could only be accomplished by an amendment of the law. That is not the office of a treasury regulation.

In *United States* v. *Symonds*, 120 U. S. 46, the law provided with regard to naval officers' pay for services at sea, that "no service shall be regarded as sea service except such as shall be performed at sea." (R. S., sec. 1571.) It was held that the Secretary of the Navy had no power to abrogate this provision of section 1571 by redefining sea service. "He may," said the court, "establish regulations in execution of, or supplementary to, but not in conflict with, the statutes defining his powers or conferring rights upon others" (p. 49).

In *Williamson* v. *United States*, 207 U. S. 425, 456, 462, it was held that the General Land Office could not impose restrictions and requirements upon entrymen under the Timber and Stone Act, 20

Stat. 89, which the act itself did not require, and thus deprive the entryman of a right which the act by necessary implication conferred upon him. The court said (p. 462):

> * * * True it is that in the concluding portion of sec. 3 of the timber and stone act it is provided that "effect shall be given to the foregoing provisions of this act by regulations to be prescribed by the Commissioner of the General Land Office." But this power must in the nature of things be construed as authorizing the Commissioner of the General Land Office to adopt rules and regulations for the enforcement of the statute, and cannot be held to have authorized him, by such an exercise of power, to virtually adopt rules and regulations destructive of rights which Congress had conferred.

The effect of these cases is well summed up in *Bong* v. *Campbell Art Co.*, 214 U. S. 236, 248, as follows:

> * * * In *Morrill* v. *Jones*, 106 U. S. 466; *Campbell* v. *United States*, 107 U. S. 407; *Williamson* v. *United States*, 207 U. S. 425, this court decided that where the Secretary of the Treasury or Secretary of the Interior is authorized to make regulations in aid of the law, he cannot make regulations which defeat the law.

No comment is needed to show that the case at bar does not involve this doctrine.

5. *The power delegated to the Secretaries was constitutional.*

It was argued in the court below that if the power to make regulations was conferred, as claimed by the Government, it was a delegation of the law-making power and therefore violated the Constitution.

In view of recent decisions of this court, little time need be spent in demonstrating the unsoundness of this contention. Aside from the cases which may be distinguishable as merely conferring the power to fix primary standards (*St. Louis & Iron Mountain Ry.* v. *Taylor*, 210 U. S. 281, 287; *Buttfield* v. *Stranahan*, *supra*), or to ascertain and declare the event upon which the particular statute was to take effect (*Field* v. *Clark*, 143 U. S. 649, 693), or as delegating the quasi-judicial power to declare a particular act violative of the statute (*Union Bridge Co.* v. *United States*, 204 U. S. 364), it is now established beyond controversy that an administrative officer may be authorized, in carrying out the general principles of a statute, to make regulations whose violation constitutes a criminal offense.

In the *Kollock* case, 165 U. S. 526, the law taxing oleomargarine required it to be packed in wooden boxes, " marked, stamped, and branded as the Commissioner of Internal Revenue, with the approval of the Secretary of the Treasury, shall prescribe."

A violation of this provision was made punishable by fine and imprisonment. *Held*, this was not a delegation of legislative power.

In *United States* v. *Grimaud*, 220 U. S. 506, 509, the act establishing forest reserves, 26 Stat. 1103, as amended by 30 Stat. 35, and 33 Stat. 628, authorized the Secretary of Agriculture to—

> make provisions for the protection against destruction by fire and depredations upon the public forests and forest reservations * * *; and he may make such rules and regulations and establish such service as will insure the objects of such reservation, namely, to regulate their occupancy and use, and to preserve the forests thereon from destruction; and any violation of the provisions of this act or such rules and regulations shall be punished as prescribed in Rev. Stat., sec. 5388.

Under this the Secretary made a regulation forbidding the grazing of sheep on such reservations without his permission. The defendants were indicted for violating this regulation. *Held*, the delegation of power was constitutional and the regulation was proper. The court said (p. 516):

> * * * in authorizing the Secretary of Agriculture to meet these local conditions Congress was merely conferring administrative functions upon an agent, and not delegating to him legislative power.

Again (p. 522):

> * * * a violation of reasonable rules regulating the use and occupancy of the property is made a crime, not by the Secretary, but by Congress. The statute, not the Secretary, fixes the penalty.

See also *United States* v. *Breen* (C. C. La.) 40 Fed. 402.

In the light of these authorities it can hardly be questioned that Congress was within its rights in delegating to the Secretaries the power to make regulations having the force of law in order to effect the purposes of the act.

III.

The statement on the label of each package that no acetanilid was contained therein was false and misleading.

1. The libel charges that this statement is false and misleading, because it "imports and signifies that there is no quantity or proportion of any derivative of acetanilid contained in said drug." (R. 3.) Defendant meets this charge with the assertion that the statement on the label is literally true, and therefore can not be false or misleading. This is a *non sequitur*. A statement may be misleading within the meaning of section 8 even though it is literally accurate, and the courts have substantially so held. It must be remembered that the language of the section is in the alternative, "false or misleading in any particular." As the court in

The court said (p. 486):

> * * * It is not so much a question of chemistry as of popular comprehension. We would not have any pure food laws if we were all chemists, because then we would be able to find out for ourselves what the thing was we were buying.

United States v. *Morgan* (C. C. N. Y.), 181 Fed. 587 (reversed on other grounds, 222 U. S. 274):

"Spring Water"

upon bottles of Croton water, with mineral salts and carbonic acid gas added.

United States v. *Ten Barrels of Vinegar* (D. C. Wis.), 186 Fed. 399:

"Saratoga Brand vinegar, a blend of pure boiled apple cider and distilled vinegar"

upon a mixture of distilled vinegar and boiled apple cider, as calculated to lead the purchaser to believe that cider vinegar was an ingredient.

Frank v. *United States* (C. C. A., 6th C.), 192 Fed. 864:

"Compound White Pepper"

upon packages containing a mixture of white pepper and other ingredients.

United States v. *Seventy-five Boxes of Alleged Pepper* (D. C. N. J.), 198 Fed. 934:

"Pure Pepper"

on packages of ground black pepper and long pepper mixed, it being established that the term "pure

United States v. *100 Cases of Tepee Apples* (D. C. Mo.), 179 Fed. 985, 987, remarked:

> Deception is seldom practiced by a literal falsehood, but is usually joined with some truth, so that the entire statement will deceive.

The courts have liberally construed this provision of section 8 to include statements calculated to deceive and mislead the purchaser without direct prevarication. In the following cases the labels mentioned were held to be misleading and the packages misbranded in consequence:

Brina v. *United States* (C. C. A., 2d C.), 179 Fed. 373:

> The phrase "Salad Oil" *held prima facie* to mean "Olive Oil," and hence a verdict finding its use on a can of cotton-seed oil misleading, sustained.

United States v. *100 Cases of Tepee Apples* (D. C. Mo.), *supra:*

> "Tepee apples. Packed by C. H. Godfrey & Son, Benton Harbor and Watervliet, Mich.,"

upon canned apples packed in Michigan but grown in Arkansas.

United States v. *Scanlon* (D. C. Ohio) 180 Fed. 485:

> "Western Reserve Ohio Blended Maple Syrup." "This syrup is made from the sugar maple tree and cane sugar"

upon packages of syrup made from cane sugar flavored with an extract of chopped maple wood.

pepper" as used in the trade means black pepper. The court held that the words "pure pepper" should be given their ordinary and customary meaning rather than a technical meaning, saying (p. 935):

> It is difficult to perceive * * * what practical efficiency the statute would have or what protection it would afford if the public were required to have scientific and technical knowledge as to the derivation and nomenclature of the various food and drug products. The ordinary purchaser, unless he could rely upon the common and generally understood signification of a label, could never be certain of what he was buying.

Schraubstadter v. *United States* (C. C. A., 9th C.), 199 Fed. 568, 569:

> "Extra Dry Champagne" and "Champagne Brand Defleur Fils and Cie. Grand Vin Royal,"

upon a bottle of domestic champagne, as tending to lead the consumer to believe that it was a foreign product.

If the principle announced and followed in these cases be sound, it seems to cover the present libel.

2. As has been seen, the public would be deprived of the information which Congress intended it to have if the defendant were allowed to omit from his labels the statement that his product contains a derivative of acetanilid. *A fortiori* then, the public

is misled by the affirmative assertion that the drug "contains no acetanilid"—a statement which would import to the unlearned consumer that no derivative of acetanilid was contained therein. Since both the parent substance and the derivative are within the mischief against which section 8 was directed, the defendant should not be permitted to take active advantage of the public's ignorance.

The court below, it is submitted, misconceived the attitude of the Government upon this point. Its discussion proceeds wholly upon the assumption that the label was claimed to be misleading because in fact acetphenetidin "necessarily contains some appreciable quantity or proportion" of acetanilid. (R. 20–21.) This was not primarily, nor finally, the position taken by the United States attorney. The contention was there, as here, that the label was misleading because it led the purchaser to believe that no derivative of acetanilid was contained in Antikamnia tablets.

It may be conceded that the charge in the libel, that the label is false and misleading for the reason stated, is an inference of the pleader which is not admitted by the exceptions. We also assume for the purposes of this argument, without admitting, that whether or not the label was misleading in this particular is a question of law which the court may decide upon demurrer,

and not one of fact to be found by the jury or the court sitting as a jury.

Frank v. *United States, supra.*

United States v. *10 Barrels of Vinegar, supra.*

Contra:

Brina v. *United States, supra.*

Schraubstadter v. *United States, supra.*

Von Bremen v. *United States,* (C. C. A., 2d C.) 192 Fed. 904.

We rely upon the natural import of the language used and a construction of the statute in the light of its purpose.

3. The phrase "false or misleading in any particular" was aimed at such false statements "as determine the identity of the article, possibly including its strength, quality, and purity * * *." *United States* v. *Johnson*, 221 U. S. 488, 497. This aim would be defeated in the present case if this branch of the libel were held defective.

CONCLUSION.

The judgment below was erroneous and should be reversed.

JOHN W. DAVIS,
Solicitor General.

KARL W. KIRCHWEY,
Attorney.

DECEMBER, 1913.

○

Supreme Court of the United States

OCTOBER TERM, 1913.

No. 118.

THE UNITED STATES OF AMERICA, *Plaintiff in Error and Appellant,*

vs.

THE ANTIKAMNIA CHEMICAL COMPANY, *Defendant in Error and Appellee.*

IN ERROR TO AND ON APPEAL FROM THE COURT OF APPEALS OF THE DISTRICT OF COLUMBIA.

BRIEF FOR THE DEFENDANT IN ERROR AND APPELLEE.

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PRESS OF BYRON S. ADAMS, WASHINGTON, D. C.

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STATEMENT.

This case is stated on pages two to eight, both inclusive, of the brief filed to dismiss or affirm, but we will make a brief statement of the case again, and show the points raised on the merits.

This is an appeal from a writ of error to the Court of Appeals of the District of Columbia from a judgment of that court sustaining a judgment of the Supreme Court of the District of Columbia, sitting as a district court, which judgment of the Supreme Court of the District of Colum-

bia sustains certain exceptions and objections to a libel filed by the United States for the seizure and condemnation of one hundred packages, more or less, of Antikamnia Tablets belonging to the defendant in error and appellee. The judgment dismisses the libel, discharges the goods from seizure, and orders a return thereof to the defendant in error and appellee. The substance of the libel describing the packages to be seized is as follows (Record, p. 2):

> "Twenty packages, more or less, of said drug, labelled and branded as follows: 'Antikamnia Tablets, containing 305 grains of acetphenetidin, U. S. P. per ounce, Guaranteed by the Antikamnia Chemical Company, under the Food and Drugs Act, June 30, 1906. U. S. Serial Number 10. The Antikamnia tablets in this original ounce package contain no acetanilid, antifebrin, antipyrin, morphine, opium, codein, heroin, cocaine, alpha or beta eucaine, arsenic, strychnine, chloroform, cannabis indica, or chloral hydrate. Antikamnia tablets five grains. One ounce Antikamnia Tablets. Manufactured in the United States of America by the Antikamnia Chemical Co., St. Louis, U. S. A.'
>
> "Also seventy packages, more or less, of said drug, labelled and branded as follows: 'Antikamnia and Codein Tablets. Contain 296 grains acetphenetidin, U. S. P. per ounce. Contain 18 grains sulp. codein per ounce. Guaranteed by the Antikamnia Chemical Company under the Food and Drugs Act, June 30, 1906, U. S. Serial number 10. The Antikamnia and Codein tablets in this original ounce package contain no acetanilid, antifebrin, antipyrin, morphine, opium, heroin, cocaine, alpha, or beta eucaine, arsenic, strychnine, chloroform, cannabis indica, or chloral hydrate. One ounce Antikamnia and Codein Tablets. Manufactured in the United States of America by the Antikamnia Chemical Co., St. Louis, U. S. A.'

"Also ten other packages, more or less, of said drug, labelled and branded as follows: 'Antikamnia and Quinine Tablets. Contain 165 grains acetphenetidin, U. S. P. per ounce. Guaranteed by the Antikamnia Chemical Company, under the Food and Drugs Act, June 30, 1906. U. S. Serial Number 10. The Antikamnia and Quinine Tablets in this original ounce package contain no acetanilid, antifebrin, antipyrin, morphine, opium, codein, heroin, cocaine, alpha or beta eucaine, arsenic, strychnine, chloroform, cannabis indica, or chloral hydrate. One ounce Antikamnia and Quinine Tablets. Manufactured in the United States of America by the Antikamnia Chemical Co., St. Louis, U. S. A.'"

The libel then charges that the aforesaid packages are misbranded in violation of the Act of Congress approved June 30, 1906 (Record, p. 3),

"BECAUSE EACH AND ALL OF SAID PACKAGES OF DRUG CONTAIN A LARGE QUANTITY AND PROPORTION OF ACETPHENETIDIN WHICH YOUR LIBEL CHARGES IS A DERIVATIVE OF ACETANILID, AND THAT UNDER THE PROVISIONS IN SAID ACT OF CONGRESS *AND OF THE REGULATIONS LAWFULLY MADE THEREUNDER*, IT IS PROVIDED AND REQUIRED THAT THE LABEL ON EACH OF SAID PACKAGES SHOULD BEAR A STATEMENT THAT THE ACETPHENETIDIN CONTAINED THEREIN IS A DERIVATIVE OF ACETANILID; AND YET YOUR LIBELLANT CHARGES THAT EACH OF SAID PACKAGES FAIL TO BEAR A STATEMENT IN ANY FORM THAT THE ACETPHENETIDIN CONTAINED THEREIN IS A DERIVATIVE OF ACETANILID, OR THAT THE SAID DRUG CONTAINS ANY DERIVATIVE OF ACETANILID."

"Your libellant further charges that each and all of said packages of drug are further misbranded, in that the labels thereon are false and misleading, for the reason that each and all of said labels bear the statement *that no acetanilid is contained therein*, and that said statement imports and signifies that there is *no quantity or proportion of any derivative of acetanilid contained in said drug*."

To this libel the defendant in error and appellee, The Antikamnia Chemical Company, having been made defendant by order of court, filed certain exceptions and objections, which said exceptions and objections are as follows (Record, p. 6):

"1. That said packages referred to in said libel are not misbranded in violation of the Act of Congress approved June 30, 1906, entitled 'The Food and Drugs Act,' and are not liable to confiscation and condemnation under said Act, because each and all of said packages are properly marked and properly state the proportion of acetphenetidin contained therein; and that they are properly labeled under said Act.

2. That the said Act does not require that the label on each of said packages should bear a statement that the acetphenetidin contained therein is a derivative of acetanilid, nor is it necessary under said act that a derivative of any parent substance should state that it is a derivative of such substance, provided the derivative itself is named by its proper name.

3. That the said packages are not misbranded, in that each and all of the said labels bear the statement that no acetanilid is contained therein, because, according to the allegation of said libel, there is nothing in said statement that is in any way false and misleading, nor does said statement import or signify that there is no quantity or pro

portion of any derivative of acetanilid contained in said drug.

4. That said statement on said packages that each and all of said labels bear the statement that no acetanilid is contained therein is in no way false or misleading, because said libel does not allege that there is any acetanilid in said packages, and, therefore, said statement, instead of being false and misleading, is, according to the allegations of said libel, true.

5. That said libel does state that in said packages is contained acetphenetidin; and the other statement on said package that said package contains no acetanilid could in no way be false and misleading because, according to the allegations of said libel, the same is true.

6. That said libel charges that acetphenetidin is a derivative of acetanilid, but does not charge that there is any acetanilid in acetphenetidin, and, therefore, the statement as contained on the label of said packages, that there is no acetanilid contained in said packages, is, according to the averments and allegations of said libel, true.

7. That said Act of Congress of June 30, 1906, provides in Section 8:

> * * * 'or if the package fail to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate or acetanilid or any deriative or preparation of any such substance contained therein.'

And does not provide that there should be added to any derivative of any such substance as contained therein the name of said parent substance; and said Act of Congress cannot be added to or enlarged by requiring this defendant, or any person, to add to a known substance the

fact that the said is a derivative of any of the substances mentioned in the above paragraph.

8. Defendant further objects and excepts to the following paragraph in Section 3 of said libel:

> 'Because each and all of said packages of drug contain a large quantity and proportion of acetphenetidin, which your libelant charges is a derivative of acetanilid, and that under the provisions of the said Act of Congress and of the regulations lawfully made thereunder, it is provided and required that the label on each of said packages should bear a statement that the acetphenetidin contained therein is a derivative of acetanilid; and yet your libellant charges that each and all of said packages fail to bear a statement in any form that the acetphenetidin, contained therein, is a derivative of acetanilid, or that the said drug contains any derivative of acetanilid.'

And says that the same is bad in substance because there is nothing in said Act of Congress, approved June 30, 1906, that requires labeling of the said packages as set out in said paragraph.

9. Defendant further objects and excepts to the following paragraph in Section 3 of said libel:

> 'Your libelant further charges that each and all of said packages of drug are further misbranded, in that the labels thereon are false and misleading, for the reason that each and all of said labels bear the statement that no acetanilid is contained therein, and that said statement imports and signifies that there is no quantity or proportion of any derivative or acetanilid contained in said drug.'

and says that the said is bad in substance because it says that in said libel there is no allegation, either direct or indirect, that there is any acetanilid contained in said drug,

and because the statement that there is no acetanilid contained in said drug in no way imports or signifies that there is no quantity or proportion of a derivative or acetanilid."

At the time of the filing of these exceptions there was some uncertainty as to whether or not exceptions or demurrers should be filed, exceptions, however, being equivalent to a demurrer. Since filing them this court has decided, in the case of Four hundred and forty-three cans of egg product, 226 U. S., 172, that the proceeding should be as at law, and therefore these exceptions should be treated as a demurrer to the libel. Upon the hearing on these exceptions and objections the Supreme Court of the District of Columbia sustained the same and dismissed the libel (Record, p. 8). From this decree an appeal was taken to the Court of Appeals of the District of Columbia (Record, p. 8), and that court (Record, p. 21), on May 29, 1911, affirmed the judgment of the Supreme Court of the District of Columbia, and the case is now here before this court on a writ of error and appeal.

Argument.

The exceptions and objections (demurrer) raised three propositions to be considered:

I. Does the libel charge a misbranding of the article mentioned therein within the meaning of the Act of June 30, 1906? Is there anything in the Act that requires the adding thereto of the words, "derivative of"—(naming the parent substance)?

II. If there is nothing in the Act that requires the adding thereto the words, "derivative of"—(naming the parent substance), when the packages describe the derivative by its name, does the Act give to the several secretaries, under Section 3, the right to promulgate a regulation requiring such statement, and provide for a punishment of a viola-

tion of such regulation by a forfeiture of goods or a criminal prosecution?

III. Is the statement on the labels of the package that no acetanilid is contained therein false and misleading because it, the said statement, *imports and signifies* that there is no quantity or proportion of any derivative of acetanilid contained in said drug?

I.

DOES THE LIBEL CHARGE A MISBRANDING OF THE ARTICLE MENTIONED THEREIN WITHIN THE MEANING OF THE ACT OF JUNE 30, 1906? IS THERE ANYTHING IN THE ACT THAT REQUIRES THE ADDING THERETO OF THE WORDS "DERIVATIVE OF"—(NAMING THE PARENT SUBSTANCE)?

In considering this first proposition we will treat it under three heads:

(A) The statute creates a new criminal offense;

(B) The statute creating a criminal offense and providing for a punishment either of a person or of a person's goods, is there sufficient in the statute to compel the adding to the derivative the name of the parent substance, when the name of that derivative appears on the label?

(C) No prosecution can be had under a statute unless its mandates are so clearly expressed that any ordinary person can determine in advance what he may or what he may not do under it.

(A.)

The Statute Creates a New Criminal Offense.

Section 1 of the Act provides:

> "That it shall be unlawful for any person to manufacture within any Territory or the District of Co-

lumbia, any article of food or drug which is adulterated or misbranded, *within the meaning of this Act;* and any person who shall violate any of the provisions of this section shall be guilty of a misdemeanor, and for each offense shall, upon conviction thereof, be fined not to exceed five hundred dollars or shall be sentenced to one year's imprisonment, or both such fine and imprisonment, in the discretion of the court, and for each subsequent offense and conviction thereof shall be fined not less than one thousand dollars or sentenced to one year's imprisonment, or both such fine and imprisonment, in the discretion of the court."

Section 2 provides:

"That the introduction into any State or Territory or the District of Columbia from any other State or Territory or the District of Columbia, or from any foreign country, or shipment to any foreign country of any article of food or drug which is adulterated or misbranded, within the meaning of this Act, is hereby prohibited; and any person who shall ship or deliver for shipment from any State or Territory or the District of Columbia to any other State or Territory or the District of Columbia, or to a foreign country, or who shall receive in any State or Territory or the District of Columbia from any other State or Territory or the District of Columbia, or foreign country, and having so received, shall deliver, in original unbroken packages, for pay or otherwise, or offer to deliver to any other person, any such article so adulterated or misbranded within the meaning of this Act, or any person who shall sell or offer for sale in the District of Columbia or the Territories of the United States any such adulterated or misbranded foods or drugs, or export or offer to export the same to any foreign country, shall be guilty of a misdemeanor, and for such offense be fined not exceeding two hundred dollars for the first offense, and upon conviction for each subsequent offense not exceeding three hundred dollars,

or be imprisoned not exceeding one year, or both in the discretion of the court: Provided, That no article shall be deemed misbranded or adulterated within the provisions of this Act when intended for export to any foreign country and prepared or packed according to the specifications or directions of the foreign purchaser, when no substance is used in the preparation or packing thereof in conflict with the laws of the foreign country to which said article is intended to be shipped; but if said article shall be in fact sold for or offered for sale for domestic use or consumption, then this proviso shall not exempt said article from the operation of any of the other provisions of this Act."

Section 3 provides:

"That the Secretary of the Treasury, the Secretary of Agriculture, and the Secretary of Commerce and Labor shall make uniform rules and regulations for carrying out the provisions of this Act, including the collection and examination of specimens of foods and drugs manufactured or offered for sale in the District of Columbia, or in any Territory of the United States, or which shall be offered for sale in unbroken packages in any State other than that in which they shall have been respectively manufactured or produced, or which shall be received from any foreign country, or intended for shipment to any foreign country, or which may be submitted for examination by the chief health, food or drug officer of any State, Territory, or the District of Columbia, or at any domestic or foreign port through which such produce is offered for interstate commerce, or for export or import between the United States and any foreign port or country."

Section 10 provides:

"That any article of food, drug or liquor that is adulterated or misbranded within the meaning of this

Act, and is being transported * * * or if it be sold or offered for sale in the District of Columbia * * * shall be liable to be proceeded against in any district court of the United States within the district where the same is found, and seized for confiscation by a process of libel for condemnation. And if such article is condemned as being adulterated or misbranded * * * within the meaning of this Act, the same shall be disposed of by destruction or sale, as the said court may direct, and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States, but such goods shall not be sold in any jurisdiction contrary to the provisions of this Act or the laws of that jurisdiction; provided, however, that upon the payment of the costs of such libel proceedings, the execution and delivery of a good and sufficient bond to the effect that such articles shall not be sold or otherwise disposed of contrary to the provisions of this Act * * * the court may by order direct that such articles be delivered to the owner thereof."

Section 8, as it stood at the time of this prosecution, provides:

Sec. 8. "That the term 'misbranded,' as used herein, shall apply to all drugs, or articles of food, or articles which enter into the composition of food, the package or label of which shall bear any statement, design, or device regarding such article, or the ingredients or substances contained therein, which shall be false or misleading in any particular, and to any food or drug product which is falsely branded as to the State, Territory, or country in which it is manufactured or produced."

"That for the purposes of this Act an article shall also be deemed to be misbranded:

"In the case of drugs:

"First. If it be an imitation of or offered for sale under the name of another article.

> "Second. If the contents of the package as originally put up shall have been removed, in whole or in part, and other contents shall have been placed in such package, or if the package fails to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivatives or preparation of any such substances contained therein."

The seizure in this case must be, if the seizure is to be sustained, a violation of that part of Section 8 which reads as follows:

> "Second. * * * or if the package fails to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any such substances contained therein."

In considering the question as to whether or not this statute creating a new crime was or was not a penal statute, the Court of Appeals of the District of Columbia, in this case (37 App., D. C., 350), said:

> "A preliminary contention on behalf of the appellants is that the Act, being remedial and not penal, should be liberally construed. This contention seems to be of little or no practical importance in the present case, as the substantial question presented is one of power rather than of construction. Without discussion, therefore, it may be said of the Act, while it contains penal provisions without which it could not be enforced, was enacted to remedy the great mischief resulting from the unrestricted sale of adulterated drugs and articles of food, and ought to be given, where possible, a construction that would affect the general legislative intent."

From an examination of the several sections of the statute, it will, however, be seen that the Food and Drugs Act of June 30, 1906, is penal in so far as it affects persons who violate that statute. Section 1 of the Act provides that it shall be unlawful for any person to manufacture within any Territory or the District of Columbia, any article of food or drug which is adulterated or misbranded, within the meaning of this Act; and any person who shall violate any of the provisions of this section shall be guilty of a misdemeanor, and for each offense shall, upon conviction thereof, be fined not to exceed five hundred dollars or shall be sentenced to one year's imprisonment, or both such fine and imprisonment, in the discretion of the court, and a heavier penalty is imposed for a second offense.

Section 2 punishes by fine for the first offense and by fine and imprisonment, or both, in the discretion of the court, for the second offense, any one who shall sell or offer for sale in the District of Columbia any such adulterated or misbranded foods or drugs, referring to any article of food or drug adulterated or misbranded "within the meaning of this Act."

Section 10 provides for the seizure of any article of food or liquor that is "adulterated or misbranded within the meaning of this Act"; and provides for its destruction. That a proceeding under Section 10 is a criminal proceeding has been established by the authorities that had this section under consideration. The construction of this Act was before this court in the case of Hipolite Egg Company, Claimant, vs. United States, 220 U. S., 45-60. In that case this court say:

> "The statute declares that it is one 'for preventing * * * the transportation of adulterated * * * foods * * * and for regulating traffic therein'; and, as we have seen, Section 2 makes the shipper of them

> criminal and Section 10 subjects them to confiscation, and, in some cases, to destruction, so careful is the statute to prevent a defeat of its purpose. In other words, transportation in interstate commerce is forbidden to them, and, in a sense, they are made culpable as well as their shipper."

Again they say:

> "We are dealing, it must be remembered, with illicit articles, articles which the law seeks to keep out of commerce, because they are debased by adulteration, and which punishes them (if we may so express ourselves) and the shipper of them."

In the case of the United States vs. O. H. Johnson, decided by the District Court of the United States for the Western District of Missouri, Phillips, District Judge, in quashing an indictment under Section 1 of the Food and Drugs Act, said (177 Federal Reporter, 313):

> "As this is a criminal statute creating a new offense, it must be strictly construed and applied. It must be constrained to its express reasonable intendment, otherwise the court by mere construction may extend its operations far beyond the legislative intent."

In considering what is a penal statute, this court, in Huntington vs. Attrill, 146 U. S., 667, 668 and 669, say:

> "Penal laws, strictly and properly, are those imposing punishment for an offense committed against the State, and which, by the English and American Constitutions, the executive of the State has the power to pardon. Statutes giving a private action against the wrong-doer are sometimes spoken of as penal in their nature, but in such cases it has been pointed out that neither the liability imposed nor the remedy given is strictly penal.

"The test whether a law is penal, in the strict and primary sense is whether the wrong sought to be redressed is a wrong to the public, or a wrong to the individual, according to the familiar classification of Blackstone: 'Wrongs are divisible into two sorts of species: private wrongs and public wrongs. The former are an infringement or privation of the private or civil rights belonging to individuals, considered as individuals; and are thereupon frequently termed civil injuries: the latter are a breach and violation of public rights and duties, which affect the whole community, considered as a community; and are distinguished by the harsher appellation of crimes and misdemeanors.' 3 Bl. Com., 2."

Again in Choutau vs. United States, 102 U. S., 603, the court say:

"Admitting that the penalty may be recovered in a civil action, as well as by a criminal prosecution, it is still as a punishment for the infraction of the law. The term penalty involves the idea of punishment, and its character is not changed by the mode in which it is inflicted, whether by a civil action or a criminal prosecution."

In Lagler vs. Bye, 42 Ind. App., 592, the court say:

"A penal statute is one which inflicts the forfeiture for transgressing its provisions. It involves the idea of punishment, and its character is not changed by the mode in which it is inflicted whether by civil or criminal procedure."

In Diversey vs. Smith, 103 Ill., 390, the court say:

"Sedgwick says, 'penal statutes are acts by which a forfeiture is imposed for transgressing the provisions of the act.' And moreover adds, 'A penal law may

> also be remedial; and the statute may be remedial in one particular, and penal in another.' (Statute and Const. Law, 41.) In Potter's Dwarris on Statutes, p. 74, it is said: 'Penal statute is one which imposes a forfeiture or penalty for transgressing its provisions or for doing a thing prohibited.' It is the effect and not the form of the statute which is to be considered; and when its object is clearly to inflict a punishment on the party for violating it, *i. e.*—doing what is prohibited, or failing to do what is commanded to be done —it is penal in its character—and the circumstances that in punishing, remedy is likewise afforded to those having an interest in the observance of the statute is unimportant."

The proceeding in the Hipolite Egg Company case was a proceeding under Section 10; and this court, in declaring that the section punished the goods, followed its own decisions holding that a proceeding *in rem* to establish a forfeiture is a criminal or quasi criminal proceeding.

The leading case on this question is Boyd vs. United States, 116 U. S., 616, which holds that proceedings in seizures and forfeitures are so far criminal as to come within the meanings of the Fourth Amendment to the Federal Constitution. At page 634, Mr. Justice Bradley said:

> "As therefore suits for penalties and forfeitures, incurred by the commission of offenses against the law, are of this quasi criminal nature, we think that they are within the reason of criminal proceedings for all the purposes of the Fourth Amendment of the Constitution and of that portion of the Fifth Amendment which declares that no person shall be compelled in any criminal case to be a witness against himself; and we are further of opinion that a compulsory production of the private books and papers of the owner of goods sought to be forfeited in such a suit is compelling him to be a witness against himself, within the meaning of

> the Fifth Amendment to the Constitution; and is the equivalent of a search and seizure, and an unreasonable search and seizure, within the meaning of the Fourth Amendment."

In the case of Coffey vs. United States, 116 U. S., 436, this court held that where for the same act there were instituted (1) a proceeding *in rem* for forfeiture for violations of the internal revenue laws, and (2) a criminal prosecution for violation of the internal revenue laws, both are of the same nature, and that a judgment of acquittal in the criminal prosecution for a violation of the internal revenue laws is conclusive in favor of the defendant in the proceeding *in rem*.

And in the case of Lees vs. United States, 150 U. S., 476, a suit brought to recover a penalty imposed for a violation of the Act of February 26, 1885—to prohibit the importation and migration of foreigners and aliens, under contract or agreement to perform labor in the United States, its Territories, and the District of Columbia—was held to be a criminal proceeding. The court said:

> "This, though an action civil in form, is unquestionably criminal in its nature and in such a case a defendant cannot be compelled to be a witness against himself. It is unnecessary to do more than to refer to the case of Boyd vs. United States, 116 U. S., 616. The question was fully and elaborately considered by Mr. Justice Bradley in the opinion delivered in that case."

Again in the case of Hepner vs. United States, 213 U. S., 111, this court say:

> "In the latter case (Boyd vs. United States) it was adjudged that penalties and forfeitures incurred by the commission of offenses against the law are of such

quasi criminal nature that they come within the reason of criminal proceedings for the purposes of the Fourth Amendment to the Constitution and of that part of the Fifth Amendment declaring that no person shall be compelled in any criminal case to be a witness against himself."

From these authorities, it conclusively appears that this Act is a penal statute. It punishes not only the person, but under Section 10 makes the articles culpable and punishes them by condemnation, or, if the court think necessary, by a destruction of the articles themselves.

On the question of construction of these statutes which has been so often before the courts we will refer only to a few leading authorities on the subject.

In the case of United States vs. Harris, 177 U. S., 305, a suit was brought by the United States against Harris and others, receivers of the Philadelphia & Reading Railroad Company, to recover a penalty in the sum of $500 for an alleged violation of certain sections of the Revised Statutes. The sections provided for the punishment of a railroad company for cruelty to animals while in transit. The contention was that the words "any company" in the statute referred to the receivers of a railroad company. This court held that receivers, not being mentioned in the statute, were not liable, and in arriving at that conclusion, said:

"We cannot better close this discussion than by quoting the language of Chief Justice Marshall, in the case of United States vs. Wiltberger, 5 Wheat., 76:

"'The rule that penal laws are to be construed strictly is perhaps not much less old than construction itself. It is founded on the tenderness of the law for the rights of individuals, and on the plain principle that the power of punishment is vested in the legis-

lative and not in the judicial department. It is the legislature, and not the court, which is to define a crime and ordain its punishment. It is said that notwithstanding this rule, the intention of the lawmaker must govern in the construction of a penal as well as other statutes. But this is not a new, independent rule which subverts the old. It is a modification of the ancient maxim and amounts to this, that though penal statutes are to be construed strictly they are not to be construed so strictly as to defeat the obvious intention of the legislature. The maxim is not to be applied so as to narrow the words of the statute to the exclusion of cases which those words, in their ordinary acceptation, or in that sense in which the legislature obviously used them, would comprehend. The intention of the legislature is to be collected from the words they employ. Where there is no ambiguity in the words there is no room for construction. The case must be a strong one indeed which would justify a court in departing from the plain meaning of words, especially in a penal act, in search of an intention which the words themselves did not suggest. To determine that a case is within the intention of a statute its language must authorize us to say so. It would be dangerous indeed, to carry the principle that a case which is within the reason or mischief of a statute is within its provisions, so far as to punish a crime not enumerated in the statute because it is of equal atrocity or of a kindred character with those which are enumerated. If this principle has ever been recognized in expounding criminal law, it has been in cases of considerable irritation, which it would be unsafe to consider as precedents forming a general rule in other cases.'"

In United States vs Lacher, 134 U. S., 629, the court, in quoting from Sedgwick, say:

"'The rule that statutes of this class (referring to penal acts) are to be construed strictly is far from being a rigid or unbending one; or rather, it has in mod-

ern times been so modified and explained away as to mean little more than that penal provisions, like all others, are to be fairly construed according to the legislative intent as expressed in the enactment; the courts refusing, on the one hand, to extend the punishment to cases which are not clearly embraced in them, and, on the other, equally refusing by any mere verbal nicety, forced construction or equitable interpretation, to exonerate parties plainly within their scope.'

"'This passage is quoted by Baron Bramwell in Attorney vs. Sillem, 2 H. & C., 532, as one in which good sense, force and propriety of language are equally conspicuous; and which is amply borne out by the authorities, English and American, which he cites.' Foley vs. Fletcher, 28 L. J. (N. S.) Ex. 100, 106; Nicholson vs. Fields, 31 L. J. (N. S.) Ex. 233; Hardcastle on Statutory Law, p. 251."

In the case of Northern Securities Company vs. United States, 193 U. S., 358, this court say:

"As early as the case of King vs. Inhabitants of Hodnett, 1 T. R., 96, Mr. Justice Buller said: 'It is not true that the courts in the exposition of penal statutes are to narrow the construction.' In United States vs. Wiltberger, 5 Wheat., 76, 95, Chief Justice Marshall, delivering the judgment of this court and referring to the rule that penal statutes are to be construed strictly said: 'It is a modification of the ancient maxim, and amounts to this, that though penal laws are to be construed strictly, they are not to be construed so strictly as to defeat the obvious intention of the legislature. The maxim is not to be so applied as to narrow the words of the statute to the exclusion of cases which those words, in their ordinary acceptation, or in that sense in which the legislature has obviously used them, would comprehend. The intention of the legislature is to be collected from the words they employ. Where there is no ambiguity in the words,

there is no room for construction.' In United States vs. Morris, 14 Pet., 464, 475, this court, speaking by Chief Justice Taney, said: 'In expounding a penal statute the court certainly will not extend it beyond the plain meaning of its words; for it has been long and well settled that such statutes must be construed strictly. Yet the evident intention of the legislature ought not to be defeated by a forced and over-strict construction. 5 Wheat., 95.' So, in The Schooner Industry, 1 Gall., 114, 117, Mr. Justice Story said: 'We are undoubtedly bound to construe penal statutes strictly; and not to extend them beyond their obvious meaning by strained references. On the other hand, we are bound to interpret them according to the manifect import of the words and the mischiefs to be within the remedial influence of the statute.' In another case the same eminent jurist said: 'I agree to that rule in its true and sober sense; and that is, that penal statutes are not to be enlarged by implication or extended to cases not obviously within their words and purport. * * * In short, it appears to me that the proper course in all these cases is to search out and follow the true intent of the legislature, and to adopt that sense of the words which harmonizes the best with the context, and promotes in the fullest manner the apparent policy and objects of the legislature.' "

From these authorities, and particularly from the authorities of this court, it appears that while this statute may have been passed for a great benefit, nevertheless, it is penal in its provisions, creates offenses for which persons may not only be punished by fine, but by imprisonment, and it also provides for the seizure of goods, and in the words of this court, punishes them, the goods, by such seizure for violating the law.

(B)

The Statute Creating a Criminal Offense, and Providing for a Punishment Either of a Person or of a Person's

Goods. Is There Sufficient in the Statute to Compel the Adding to the Derivative the Name of the Parent Substance, When the Name of that Derivative Appears on the Label?

The offense attempted to be charged against the defendant in error and appellee is alleged to be a violation of that part of Section 8 which reads as follows:

> " * * * or if the package fail to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any such substances contained therein."

Reading the section carefully, can it be said for a moment that there is anything therein that requires a person, after stating the number of grains of acetphenetidin, to add thereto the further statement that acetphenetidin is a derivative of acetanilid? Treating the exceptions as a demurrer, and treating them as raising only questions of law, these exceptions might be said impliedly to admit that acetphenetidin is a derivative of acetanilid but what is there in Section 8 of the Act that requires the manufacturer of acetphenetidin (a well-known and defined drug, being defined in the United States Pharmacopœia) to add thereto that it is a derivative of acetanilid (another drug defined in the same Pharmacopœia), and a drug which we will show in the appendix filed to this brief has been condemned by the Department itself as being an adulterant for acetphenetidin, a drug which the Department itself has said is much cheaper and more harmful than acetphenetidin? The proposition of the United States that the Act itself requires it, is repudiated by the wording of the Act. Let us again read the Act, eliminating therefrom the surplusage: "Or if the package fail

to bear a statement on the label of the quantity or proportion of * * * acetanilid or any derivative or preparation of any such substances contained therein." Now read the Act in this way: "Or if the package fail to bear a statement on the label of the quantity or proportion of any * * * acetanilid or any derivative or preparation of acetanilid." Is not this what the Act means? And, if that is so, how can the contention of the Government be sustained? To sustain it, it is said in the brief of the plaintiff in error and appellee, that these drugs are habit-forming drugs. Of this fact there is no evidence. It is further said that acetanilid and acetphenetidin are chemically alike, something with which we have nothing whatever to do. It is further said, and in the brief there is set out the effects of the use of these several drugs, that they produce the same physiological effect, something that is not alleged in the libel, and something with which we have nothing to do. In the trial of this case in the Court of Appeals, the United States District Attorney, when questioned by the court as to whether a derivative, when named, would have to be followed by the name of the parent substance, replied: "If the derivative does not follow in effect the parent, then no law would be violated if you failed to state the name of the parent substance." In other words, in order to determine whether or not you would have to name the parent substance, every individual who was labelling a drug would not only have to be a chemist, but would also have to be an expert in therapeutics and physiology in order to determine whether or not on a label there should be added, after the name of the derivative, the name of its parent. The answer of the District Attorney to the question shows the fallacy of the Government's position taken in the Court of Appeals. From an examination of the brief in this court, it would appear that the Government has abandoned that position, and now takes

the more consistent position, that wherever a derivative is named, a statement should follow that it it was derived from (naming the parent substance).

The position of the Government as to whether or not there could be a prosecution under this Act without the regulation is inconsistent with the very origin of the regulation itself. For before the regulation was framed, the matter was referred to the Attorney General of the United States, and in the reference, the Attorney General was asked for his opinion on this section of the Act by the Secretary of Agriculture, and on his opinion was based the regulation which will be hereafter considered. Attorney General Bonaparte, in his opinion, dated January 15, 1909, says:

> "In the absence, however, of regulations to this effect, I do not think you can hold a package misbranded because the name of the parent substance does not follow that of the derivative, for it would certainly be a harsh construction of a *penal provision such as this* to hold that the package and its owner shall incur the grave consequences of misbranding under the statute, because of this omission, since there is nothing in the law itself to inform the said owner that such an omission would constitute an offense."

And this position was also taken by the United States Attorney when he filed this libel. He does not charge in his libel a misbranding under the Act, but on R., p. 3, the libel says:

> "Because each and all of said packages of drug contain a large quantity and proportion of acetphenetidin, which your libellant charges is a derivative of acetanilid, and that under the provisions of said Act of Congress *and of the regulations lawfully made thereunder*, it is provided and required that the label on each of said packages should bear a statement that the acetphenetidin contained therein is a derivative of acetanilid."

This statement in the libel follows the regulation made in pursuance of the opinion of Attorney General Bonaparte, it being Food Inspection Decision 112 (R., p. 9), which said regulation reads as follows:

> "In declaring the quantity or proportion of any of the specified substances the names by which they are designated in the Act shall be used, and in declaring the quantity or proportion of derivatives of any of the specified substances, in addition to the trade name of the derivative, the name of the specified substance shall also be stated, so as to indicate clearly that the product is a derivative of the particular specified substance."

So that we have interpreting this statute to be one incapable of non-enforcement in this case, except for the regulation, the Attorney General of the United States and the United States District Attorney who filed this libel, because this libel is not filed under the general law, nor does it describe a misbranding under the Act of Congress, but it describes a misbranding "under the provisions of said Act of Congress *and of regulations lawfully made thereunder.*" So that it would appear that at no time did any official of the Government believe that a prosecution could be had under the Act itself until driven by the stress of circumstances to take this position because the position that a prosecution could be had under the regulation is untenable. It seems somewhat inconsistent to prosecute a man under a regulation made by agreement a part of the record, to have the law officer of the United States say that the regulation was necessary in order to enforce the Act, and when the regulation is attacked, to change front and say that the prosecution is not under the regulation, but that it can be had under the statute. It serves no good use to say that the

regulation is in accordance with Section 8, because that cannot aid the Government in this case. The prosecution must stand or fall under the statute, and if it takes the regulation to sustain the prosecution, then the defendant in error and appellee is prosecuted not under the statute alone, but under the statute and the regulation.

Speaking of this question, the Court of Appeals, in this case (37 App. D. C., 350), say:

> "It seems clear that this omission (referring to the addition of the parent substance) is not an express violation of the requirements of Section 8 of the Act, for the reason that the label states the true name of the drug, acetphenetidin, which, though not one of those specifically named in the section, is a derivative of one of them, acetanilid."

For these reasons it is submitted that if the prosecution in that case had been based upon the Act, and the Act alone, that the defendant in error and appellee could not have been held for the omission here charged. It certainly cannot be said for a moment that within the four corners of the Act there is anything that requires the naming of a parent substance where the derivative itself is named? The contention on the part of the Government that one drug is better known than the other is not sustained even by their own brief, because they set out in the brief the definitions of these drugs, as contained in the Pharmacopœia, the physiological effect of these drugs as stated by medical writers, and it is respectfully submitted that to the public at large the word, "acetphenetidin," is about as well known as the word "acetanilid." Both are coal tar products, one, however, according to the Government's own statements, is a much better drug and much dearer drug and much less harmful drug than the other, and just why the

Government desires to blacken the character of acetphenetidin by requiring a statement of its alleged parent, we are unable to say. Instead of assisting in carrying into effect the objects of the Pure Food Law, the Government here is retarding the carrying into effect of its objects, for if manufacturers are compelled to state, after the word "acetphenetidin," "a derivative of acetanilid," then manufacturers will cease to use acetphenetidin, and use acetanilid, and in the drugs in which these substances may be used, instead of having the drug, acetphenetidin, there will be therein the cheap product, the adulterant of acetphenetidin, acetanilid, and instead of paying a large sum of money per pound for the use of the dearer and less harmful drug, manufacturing chemists will, of course, use acetanilid, the cheaper drug.

The Government in its brief attempts to invoke the aid of judicial notice, and to try here before the court, without any issue, *ex parte*, not only the therapeutic and curative effect of these drugs, but also the physiological effect, and it further desires to show, *ex parte*, that these drugs are habit-forming drugs. If this court can take judicial notice of the matters that the Government says it can take judicial notice of, then it must notice the fact that these drugs are not one the parent of the other, because the Pure Food Law itself refers to the Pharmacopœia, and the Pharmacopœia makes these two drugs coal tar products, but in no way makes the one the lineal relative of the other. If this court can take notice of the facts which the Government maintains that it can, then it can and must notice everything contained in the appendix of this brief, which facts, among other things, show that the Government itself, through its officers in the Department of Chemistry, treated acetanilid as an adulterant of acetphenetidin, and that at the hearings before the Congress of the United States, the

officers of the United States, and other health officers testified as to the distinction between these two drugs, all of which appears in the appendix. Indeed, it might be said that everything in the appendix can be taken notice of by the court as a history of the drugs, and that this would be a proper invocation of the rule of judicial notice, but it is well settled that no court will take judicial notice of those facts which require expert knowledge, and the attempt on the part of the Government to have this court take judicial notice of the facts mentioned in their brief is an attempt to try *ex parte* the effect of these drugs upon the human system; nor is there anything in the pleadings that raises any such issue, the facts of which could be proven by the facts which the Government desires this court to take notice of judicially. If issue was joined on this libel, there would be no issue as to whether or not acetanilid and acetphenetidin are similar substances, there would be no issue that acetanilid and acetphenetidin have the same therapeutic or physiological effect. All of these questions are outside the issue involved. At a trial, if issue were joined on these libels, the plaintiff in error and appellee would not be permitted to prove any of the contentions that are now raised in their brief. It could not be shown that there was acetanilid in acetphenetidin, because no such issue is raised, and it is conceded even by the Government's brief that such statement is absolutely false, nor could the plaintiff in error or appellee put on the stand any chemist to show that these two substances were in any way chemically alike, nor could it call experts on therapeutics and physiology to show that they had the same therapeutic and physiological effect. The defendant in error and appellee would have no notice that such testimony was going to be offered, because there is nothing in the libel attempting to raise any such issue. But the plaintiff in error and appellee contends that on the hearing of exceptions and objections, the Court will take

judicial notice of what is found in the encyclopedias and dictionaries, and finding therefrom that these substances are chemically similar, have the same therapeutic effect, and have the same physiological effect, will say (*although the trial court was not asked to say, and although we were not given an opportunity to prove that such was not the fact*), that all these things are true. It is virtually an attempt to try *ex parte* the effect of these several drugs upon the human system, something that cannot be done, something that has never been done, and something that this court will not do. When we consider what might be called the second part of the libel, we will refer again to this subject and treat of the authorities on judicial notice.

It is submitted that these numerous contentions of the Government shed no light upon the real question, that is, whether or not there is sufficient in the statute to compel the adding to the derivative the name of the parent substance, when the name of the derivative appears on the label.

It is respectfully submitted that from the authorities referred to, from the decision of Attorney General Bonaparte, and from the decision of the United States Attorney, who brought this suit, that there is nothing in the law that authorizes any such prosecution.

(C)

No Prosecution Can be Had Under a Statute Unless Its Mandates Are so Clearly Expressed That Any Ordinary Person Can Determine in Advance What He May or What He May Not Do Under It.

The proceeding in this case is *quasi criminal*. A proceeding under the statute in *personam* is criminal. Article 6 of the Amendments to the Constitution provides:

> "In all criminal prosecutions the accused shall enjoy the right to a speedy and public trial by an impartial jury of the State and district wherein the crime shall have been committed, which district shall have been previously ascertained by law, and to be informed of the nature and cause of the accusation."

This Constitutional guarantee protects the individual not only in requiring the Government to produce to him a sufficient information or indictment containing the charge, but also requires the legislative department of the Government to point out to him the crime or offense with which he is charged. "In order to constitute a crime, the act must be one of which the party is able to know in advance whether it is criminal or not." Fozer vs. United States, 52 Fed. Rep., 919.

In the case of Todd vs. United States, 158 U. S., 282, the court say:

> "It is axiomatic that statutes creating and defining crimes cannot be extended to intendment, and that no act, however wrongful, can be punished under such a statute unless clearly within its terms. 'There can be no constructive offenses, and before a man can be punished, his case must be plainly and unmistakably within the statute.' United States vs. Lacher, 134 U. S., 624; Endlich on the Interpretation of Statutes, Sec. 329, 2d ed.; Pomeroy's Sedgwick on Statutory and Constitutional Construction, 280."

In United States vs. Lacher, 134 U. S., 638, the court say:

> "As contended on behalf of the defendant, there can be no constructive offenses, and before a man can be punished, his case must be plainly and unmistakable within the statute."

In the case of State vs. Mann, 2 Oregon, 241, the court say:

> "A crime or public offense is some act prohibited by law; and it is a well-settled rule of law that no one can be punished for doing an act unless it clearly appears that the act sought to be punished comes clearly within both the spirit and letter of the law prohibiting it. The act constituting the offense should be clear, and specifically described in the statute, and with sufficient certainty at least to enable the court to determine from the words used in the statute whether the act charged in the indictment comes within the prohibition of the law."

In the case of Brown vs. State, 131 Wisconsin, 543, reading from page 548 the court say:

> "It is a most fundamental canon of criminal legislation that a law which takes away a man's property or liberty as a penalty for an offense, must so clearly define the acts upon which the penalty is denounced, that no ordinary person can fail to understand his duty, and the departure therefrom which the law attempts to make criminal. One cannot be said to wilfully violate a statute which is so contradictory or blind that he must guess or conjecture what is his duty thereunder."

In United States vs. Capital Traction Company, 34 App. D. C., 597, the court say:

> "This Court in the case Czarra vs. Medical Supers, 25 App. D. C., 443, construing a statute which provided that any licentiare of the board was subject to have his license revoked upon being found guilty of unprofessional or dishonorable conduct, said: 'The single question to be determined is whether, independently of the causes mentioned "unprofessional or

dishonorable conduct," as declared in the act, are sufficiently specific and certain to warrant a conviction thereof and the exercise of the power of revocation by the board of medical supervisors. * * *

"'In all criminal prosecutions the right of the accused to be informed of the nature and cause of the accusation against him is preserved by the 6th Amendment. In order that he may be so informed by the indictment or information presented against him, the first and fundamental requisite is that the crime or offense with which he stands charged shall be defined with reasonable precision. He must be informed by the law, as well as by the complaint, what acts or conduct are prohibited and made punishable. In the exercise of its power to regulate the conduct of the citizen, within the constitutional limitations, and to declare what shall constitute a crime or punishable offense, the legislature must inform him with reasonable precision what acts are intended to be prohibited.' To the same effect are Augustine vs. State, 41 Tex. Crim. Rep., 56; 96 Am. St. Rep., 765; 52 S. W., 77; State vs. Gaster, 45 La. Ann., 636; 12 So., 739; State vs. Mann, 2 Or., 238; *Ex parte* Jackson, 45 Ark., 158; Hewitt vs. State Medical Examiners, 148 Cal., 590; 3 L. R. A. (N. S.), 896; 113 Am. St. Rep., 315; 84 Pac., 39; 7 A. & E. Ann. Cas., 750.

"In a criminal statute, the elements constituting the offense must be so clearly stated and defined as to reasonably admit of but one construction. Otherwise, there would be lack of uniformity in its enforcement. The dividing line between what is lawful and unlawful cannot be left to conjecture. The citizen cannot be held to answer charges based upon penal statutes whose mandates are so uncertain that they will reasonably admit of different constructions. A criminal statute cannot rest upon an uncertain foundation. The crime, and the elements constituting it, must be so clearly expressed that the ordinary person can intelligently choose, in advance, what course it is lawful for him

to pursue. Penal statutes prohibiting the doing of certain things, and providing a punishment for their violation, should not admit of such a double meaning that the citizen may act upon the one conception of its requirements and the court upon another. As was said in United States vs. Reese, 92 U. S., 214, 23 L. Ed., 563: "If the legislature undertakes to define by statute a new offense, and provide for its punishment, it should express its will in language that need not deceive the common mind. Every man shoudd be able to know with certainty when he is committing a crime. * * * It would certainly be dangerous if the legislature could set a net large enough to catch all possible offenders, and leave it to the courts to step inside and say who could be rightfully detained, and who should be set at large. This would, to some extent, substitute the judicial for the legislative department of the government.'"

Having in mind these authorities, we can arrive at but one conclusion, that not only does a fair interpretation of this statute not bring the alleged misbranding mentioned in the libel within the statute, but that under the Federal Constitution, the statute must write within its four corners the acts which are to constitute a misbranding, before a prosecution can be had thereunder, and you can not read into this Act the words that the United States desires to be incorporated therein, because the attempt to do so would be in violation of a person's constitutional guarantees. Reading the statute as we have it, is it possible to say that anyone would have notice of the fact that if he mentioned a derivative, he would be compelled by the statute to state the parent. Statutes are written so that he who runs may read. Statutes are written so that citizens will know if an act committed by them is lawful or unlawful. How can anyone reading the statute know that in stating the name of a derivative, he is compelled to state the name of

the parent. The statute does not say so, the citizen has no notice that such is going to be required of him, and as the Constitution requires not only notice in the information, but notice in the law itself, you can not read into this statute any notice to a citizen that he must name the parent drug. Indeed, we have just shown that this act has been interpreted by the law department of the Government itself, as not to have in it any notice to a citizen that he should add to the name of the derivative the name of the parent substance.

And that brings us to consider our second proposition.

II.

IF THERE IS NOTHING IN THE ACT THAT REQUIRES THE ADDING THERETO THE WORDS "DERIVATIVE OF"—(NAMING THE PARENT SUBSTANCE), WHEN THE PACKAGES DESCRIBE THE DERIVATIVE BY ITS NAME, DOES THE ACT GIVE TO THE SEVERAL SECRETARIES, UNDER SECTION 3, THE RIGHT TO PROMULGATE A REGULATION REQUIRING SUCH STATEMENT, AND PROVIDE FOR A PUNISHMENT OF A VIOLATION OF SUCH REGULATION BY A FORFEITURE OF GOODS OR A CRIMINAL PROSECUTION?

In considering this proposition, we shall consider it under the following heads:

(A) The regulation adds to, alters, and amends the statute:

(B) There is no provision in the Act for punishing a misbranding in violation of *any regulation* made by the several secretaries.

(A)

The Regulation Adds to, Alters, and Amends the Statute.

Section 3 of the Act provides:

> "THAT THE SECRETARY OF THE TREASURY, THE SECRETARY OF AGRICULTURE, AND THE SECRETARY OF COMMERCE AND LABOR SHALL MAKE UNIFORM RULES AND REGULATIONS FOR CARRYING OUT THE PROVISIONS OF THIS ACT, INCLUDING THE COLLECTION AND EXAMINATION OF SPECIMENS OF FOODS AND DRUGS MANUFACTURED OR OFFERED FOR SALE IN THE DISTRICT OF COLUMBIA, OR IN ANY TERRITORY OF THE UNITED STATES, OR WHICH SHALL BE OFFERED FOR SALE IN UNBROKEN PACKAGES IN ANY STATE, OTHER THAN THAT IN WHICH THEY SHALL HAVE BEEN RESPECTIVELY MANUFACTURED OR PRODUCED, OR WHICH SHALL BE RECEIVED FROM ANY FOREIGN COUNTRY, OR INTENDED FOR SHIPMENT TO ANY FOREIGN COUNTRY, OR WHICH MAY BE SUBMITTED FOR EXAMINATION BY THE CHIEF HEALTH, FOOD, OF DRUG OFFICER OF ANY STATE, TERRITORY, OR THE DISTRICT OF COLUMBIA, OR AT ANY DOMESTIC OR FOREIGN PORT THROUGH WHICH SUCH PRODUCT IS OFFERED FOR INTERSTATE COMMERCE, OR FOR EXPORT OR IMPORT BETWEEN THE UNITED STATES AND ANY FOREIGN PORT OR COUNTRY."

In connection with this section we also read section 4:

> "That the examinations of specimens of foods and drugs shall be made in the Bureau of Chemistry of the

Department of Agriculture, or under the direction and supervision of such Bureau, for the purpose of determining from such examinations whether such articles are adulterated or misbranded within the meaning of this Act; and if it shall appear from any such examination that any of such specimens is adulterated or misbranded within the meaning of this Act, the Secretary of Agriculture shall cause notice thereof to be given to the party from whom such sample was obtained. Any party so notified shall be given an opportunity to be heard, under such rules and regulations as may be prescribed as aforesaid, and if it appears that any of the provisions of this Act have been violated by such party, then the Secretary of Agriculture shall at once certify the facts to the proper United States district attorney, with a copy of the results of the analysis or the examination of such article duly authenticated by the analyst or officer making such examination, under the oath of such officer. After judgment of the court, notice shall be given by publication in such manner as may be prescribed by the rules and regulations aforesaid."

The regulation promulgated is as follows (Record, p. 12):

"In declaring the quantity or proportion of any of the specific substances, the name by which they are designated in the act shall be used, and in declaring the quantity or proportion of the derivative of any of the specific substances, in addition to the trade name of the derivative, the name of the specific substance shall also be stated so as to indicate clearly that the product is a derivative of the particularly specified substance."

An examination of Section 3 will show that the three secretaries are given authority to make uniform rules and regulations for carrying out the provisions of this Act, including the collection and examination of specimens of

food and drug manufactured or offered for sale in the District of Columbia, etc. From this it will be seen that these regulations are merely administrative, and that no power or authority is given to the secretaries by the Act to add to or in any way enlarge the Act itself. There is nothing in Section 3 from which it could be supposed for a moment that if anyone refused to carry out the rules and regulations made by the three secretaries that it would in any way be a violation of any law. Section 4 shows conclusively that it was never intended by Section 3 to do otherwise than to have the three secretaries prescribe the rules of the Department and the administrative rules to carry into effect the Act.

Section 4, referring to the examination of specimens of foods and drugs, which examination can be made or had *under the rules and regulations* made by the three secretaries under Section 3, says such examination is for the purpose of determining "whether such articles are adulterated or misbranded *within the meaning of this Act;* and if it shall appear from any such examination that any of such specimens is adulterated or misbranded *within the meaning of this Act*, the Secretary of Agriculture shall cause notice thereof to be given," etc. And again, "*if it appears that any of the provisions of this Act have been violated* by such party, then the Secretary of Agriculture shall at once certify the facts to the proper United States district attorney, with a copy of the results of the analysis or the examination of such article." And again, after the judgment of the court, "notice shall be given by publication in such manner as may be prescribed by the rules and regulations aforesaid," referring to the administrative rules to be made by the secretaries under Section 3.

Section 5 provides:

"That it shall be the duty of each district attorney to whom the Secretary of Agriculture shall report *any violation of this Act*, or to whom any health or food or drug officer or agent of any State, Territory or the District of Columbia shall present satisfactory evidence **of *any such violation*** to cause appropriate proceedings to be commenced and prosecuted in the proper courts of the United States, without delay, for the enforcement *of the penalties as in such case herein provided*."

Section 6 says that the term, "drug," as used in *this Act*, shall include, etc.

Section 7 says that for the purposes of this Act an article shall be deemed to be adulterated, and then narrates when, under the Act, it is adulterated.

Section 8 says: "The term, 'misbranded,' as used herein, shall apply to all drugs," etc. Again, in the last paragraph of Section 8, it is said that nothing in this Act shall be construed as requiring or compelling proprietors or manufacturers of proprietary foods which contain no unwholesome added ingredients to disclose their trade formulas, except in so far as the *provisions of this Act* may require to secure freedom from adulteration or misbranding.

Section 9 says that no dealer shall be prosecuted *under the provisions of this Act* when he can establish a guaranty signed by the wholesaler, jobber, manufacturer or other party residing in the United States from whom he purchased such articles, to the effect that the same is not adulterated or misbranded *within the meaning of this Act* (designating it). Said guaranty, to afford protection, shall contain the name and address of the party or parties making the sale of such articles to such dealer, and in such case said party or parties shall be amenable to the prosecutions, fines, and other penalties which would attach, in due course, to the dealer under the provisions of this Act.

Section 10, under which this proceeding is had, says that any article of food, drug or liquor that is adulterated or misbranded *within the meaning of this Act*, etc. And again, in Section 10, "but such goods shall not be sold in any jurisdiction contrary to the *provisions of this Act* or the laws of that jurisdiction." And again, "such articles shall not be sold or otherwise disposed of contrary to the provisions of this Act," etc.

The libel charges "that under the provisions of the said Act of Congress *and of the regulations lawfully made thereunder*, the regulation referred to being the one we have just quoted; that this regulation adds to the Act there can be no doubt, for if it does not add to the Act, for what use was it made? You cannot read the Act and read in it this regulation, and, therefore, when we come to a prosecution under the Act and the regulation, necessarily the libel must allege, as it does in this case, not only a violation of the provisions of the Act under which the prosecution can only be had, but also a violation of the regulation. No stronger argument can be made in behalf of the defendant in error and appellee than the reading of the several sections herein referred to.

Section 4 provides for the examination of specimens of foods and drugs, and says who shall make such examinations, not for the purpose of determining from such examinations whether or not the regulation of the three secretaries has been violated, but to determine from such examinations whether such articles are adulterated or misbranded *within the meaning of this Act*. And if it appears from any such examination that any such specimen is adulterated or misbranded within the meaning of this Act then the Secretary of Agriculture causes a notice thereof to be given to the party from whom such sample was obtained, and any party so notified shall be given an opportunity to be heard

under such rules and regulations as may be prescribed as aforesaid (showing the regulations are merely administrative), and if it appear that any of the provisions of this Act has been violated by such party (referring to violations under the Act and not under the regulations), then the Secretary shall at once certify the facts to the proper United States district attorney * * *. After judgment of the court, notice shall be given by publication in such manner as may be prescribed by the *rules and regulations as aforesaid*. In every part of Section 4 the words, "rules and regulations" there referred to are shown to be rules and regulations for the administration of the law by the Department of Agriculture, and in the very same section it refers twice at least to an adulteration or misbranding *within the meaning of the Act*.

A departmental regulation is merely an executive act and cannot either amend, change, or add to the laws of Congress. This is well settled by the authorities. That a regulation cannot convert an act, otherwise innocent, into an offense by adding to, or altering, or amending the Act, is unquestionably the law. Section 3 of the Food and Drugs Act does not in any way permit the several Secretaries to add to, alter or amend the Act, but permits them only to make needful regulations for carrying into effect the Act as it is, and as it has been written by Congress.

The law itself sets out specifically what shall be considered a misbranding or adulteration within the meaning of the statute; and an examination of the regulation will show that it is not a regulation for the purpose of carrying the law into effect, or for administering the law, but it is a regulation that adds to the law, not requiring merely the doing a certain act in administering the law, but the doing of a certain act which the law does not require to be done and which if violated is punishable.

In the case of Morrill v. Jones, 106 U. S., 566, it was held under Section 2505, R. S., which provides that live animals especially imported for breeding purposes from beyond the seas should be admitted free of duty, upon proof thereof satisfactory to the Secretary of the Treasury and under such regulation as he might prescribe, that he had no authority to prescribe a regulation requiring that, before admitting the animals free, the Collector should be satisfied that they were of superior stock, adapted to improving the breed of the United States. The court said (p. 467):

> "The Secretary of the Treasury cannot, by his regulations, alter or amend a revenue law. All he can do is to regulate the mode of proceeding to carry into effect what Congress has enacted. In the present case, we are entirely satisfied the regulations acted upon by the Collector was in excess of the power of the Secretary. The statute clearly includes animals of all classes. The regulation seeks to confine its operation to animals of 'superior stock.' This is manifestly an attempt to put into the body of the statute a limitation which Congress did not think it necessary to prescribe. Congress was willing to admit, duty free, all animals specially imported for breeding purposes; the Secretary thought this privilege should be confined to such animals as were adapted to the improvements of breeds already in the United States. In our opinion, the object of the Secretary could only be accomplished by an amendment of the law. That is not the office of a Treasury regulation."

In United States vs. Two Hundred Barrels of Whiskey, 95 U. S., 751, 576, the Court said:

> "The regulations of the department cannot have the effect of amending the law. They may aid in carrying the law as it exists into execution, but they cannot change its positive provisions."

In the case of United States vs. Three Barrels of Whiskey, 77 Fed. Rep., 965, the law read that stamps should be affixed to a smooth surface of the barrel and covered with transparent varnish, and "such affixing and covering shall be in such manner as the Commissioner of Revenue may prescribe." The producer had covered the top of the barrels with newspaper in violation of a regulation of the Commissioner. Held, regulation void. The court said:

> "A regulation cannot have the effect of amending or changing the law. The province of the rules, laid down by the Treasury Department in accordance with the statute authorizing them is to regulate the mode of proceeding to carry into effect what Congress has enacted."

Taylor vs. Kercheval, 82 Fed. Rep., 504:

> "It needs neither argument nor citation of authority to demonstrate that neither the President nor the Civil Service Commission is clothed with legislative powers. Neither can change the law either by repeal or by making a new enactment. And it is equally elementary that Congress cannot delegate its legislative powers either to the President or the Civil Service Commission. The rules promulgated which place office deputies in the marshal's office in the classified civil service lists are not a statute nor have they the force of law. They are merely executive rules and regulations, promulgated by authority of law and are effective if at all only as rules and regulations for the internal control and government of the civil service and executive departments."

In the case of United States vs. Symonds, 120 U. S., 46, under Section 1556, R. S., providing that lieutenants in the Navy should received a stated compensation for serv-

ices performed "at sea," it was held that the Secretary of the Navy had no authority to pass a regulation defining the clause "at sea," and that, if the services were performed "at sea" within the meaning of the statute, the right of the legally established compensation was absolute and could not be destroyed by any regulation of the Secretary. The court said:

> "If the regulations of 1876 have not recognized services 'on board a practice ship at sea' as sea services, the argument in behalf of the Government would imply that they could not be regarded by the courts, or by the proper accounting officers, as sea services; in other words, that the Secretary of the Navy could fix, by order, and conclusively, what was and what was not sea service. But Congress certainly did not intend to confer authority upon the Secretary of the Navy to diminish an officer's compensation, as established by law, by declaring that to be shore service, which was, in fact, sea service, or to increase his compensation by declaring that to be sea service which was, in fact, shore service. The authority of the Secretary to issue orders, regulations, and instructions, with the approval of the President, in reference to matters connected with the naval establishment, is subject to the condition, necessarily implied, that they must be consistent with the statutes which have been enacted by Congress in reference to the Navy. He may, with the approval of the President, establish regulations in execution of, or supplementary to, but not in conflict with, the statutes defining his powers or conferring rights upon others. The contrary has never been held by this court. * * * If the services of Symonds were, in the meaning of the statute, performed 'at sea' his right to the compensation established by law for sea service is as absolute as is the right of any other officer to his salary as established by law."

In the case of Williamson vs. United States, 207 U. S., 425, Williamson was indicted for conspiring to commit the crime of subornation of perjury in proceedings for the purchase of public land under the authority of the law commonly known as the Timber and Stone Act. The statutes provide that the applicant must make an original sworn statement giving certain particulars concerning the land and declaring that his application is made not for speculation but in good faith. A second affidavit is required by the statute, in which certain facts must be stated, but in which a statement of *bona fides* is not required. The Commissioner of the General Land Office passed a regulation ordering that the applicant should make oath to his good faith in the second affidavit. The court held this regulation to be void, saying (p. 462):

> "True it is that in the concluding portion of No. 3 of the Timber and Stone Act it is provided that 'effect shall be given to the foregoing provisions of this act by regulations to be prescribed by the Commissioner of the General Land Office.' But this power must in the nature of things be construed as authorizing the Commissioner of the General Land Office to adopt rules and regulations for the enforcement of the statute, and cannot be held to have authorized him, by such an exercise of power, to virtually adopt rules and regulations destructive of rights which Congress had conferred."

In the case of Payne vs. Railway Publishing Company, 20 App., D. C., 581, under a statute providing that periodical publications, in order to be admitted as second-class mail matter "must be originated and published for the dissemination of information of a public character, or devoted to literature sciences, arts or some special industry," a regulation of the Postmaster-General restricting such pub-

lications to "such as consist of current news or miscellaneous literary matter" was held void. After quoting Morrill vs. Jones, *supra* the court said (p. 600):

> "The Postmasters-General, who for many years have been appealing to Congress for some remedy for what they designate as an abuse of the second-class mail matter system, seem also to have been of opinion that they were without authority to remedy the evil by a postal regulation. It is unnecessary for us, in the present case, to decide how far their action and their view and construction of the law are binding, if at all, upon their successors. But even if we assume that the matter now comes up for consideration for the first time, and that the Postmaster-General is now for the first time called upon to make regulations to carry the statute into effect, we are clearly of opinion that the postal regulation of July 17, 1901, so far as it assumes to add to the requirements of the statute in regard to second-class matter, is in excess of his authority, and of no validity in law."

Speaking of this question, the Court of Appeals in this case, 37 App. D. C., p. 351, said:

> "On the other hand, it is equally well settled that the power conferred to make regulations for carrying the law into effect must be exercised within the powers delegated, that is to say, confined to details for regulating the mode of proceeding to carry into effect the law as it has been enacted by Congress. It cannot be extended to amending or adding to the requirements of the act itself. (Morrill vs. Jones, 106 U. S., 466, and cases there cited.)
>
> "The decisions cited mark the general boundary line between the powers that may be delegated to administrative officers, and those that may not be. It re-

mains to determine on which side of that line the power claimed in the present case falls.

"It must be borne in mind that the Food and Drugs act (34 Stat. at L., 768, chap. 3915, U. S. Comp. Stat., Supp. 1909, p. 1187) does not confer upon executive officers the power to prescribe the forms of brands and labels upon drugs, as was done by the oleomargarin act, that was considered in Kollock's Case, *supra*. The only power conferred is that in Sec. 3, which provides that the three Secretaries named 'shall make uniform rules and regulations for carrying out the provisions of this act, including the collection and examination of specimens of foods and drugs,' etc.

"Sec. 8 declares when an article shall be deemed to be misbranded: 'First: If it be an imitation of, or offered for sale under the name of, another article. Second: * * * If (among other things) the package fail to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucain, chloroform, cannabis indica, chloral hydrate, or acentanilid, or any derivative or preparation of any such substances contained therein.'

"In so far as the regulation designates the several derivatives of the drugs enumerated in Sec. 8, and the preparations containing the same, we are of the opinion that it is within the power conferred in Sec. 3 to make uniform rules and regulations for carrying out the provisions of the act. It was not reasonably practicable for Congress to ascertain and declare these several derivatives and preparations which might then have existed, much less to anticipate those which might later come into existence and use. Having declared that the quantity or proportion of the several derivatives of the named drugs shall be stated on the labels, the ascertainment of such derivatives was a matter of detail properly confided to the executive officers in carrying out the provisions of the law. The regulation having named acetphenetidin as a derivative of acetanilid, the manufacturer complied therewith to the extent of

naming the proportion of said derivative contained in the antikamnia tablets, but did not comply with the requirement of the same that it also recite that it was, in fact, a derivative of acetanilid. The last requirement was in our opinion an amendment of, or an addition to, the act itself, and therefore beyond the powers of the executive authority. Congress reserved to itself the statement of the contents of the labels, and did not require that when a drug was a derivative merely, the name of the drug from whence derived should also be recited. Had it intended that this should be done, it would have so declared distinctly. In this respect the case is clearly differentiated from *Re* Kollock, *supra*, and comes within the rule governing the second class of cases before recited, including United States vs. Eaton, 144 U. S., 677-688, 26 L. ed., 591-594, 12 Sup. Ct. Rep., 764; and Williamson vs United States, 207 U. S., 425-462, 52 L. ed., 278-297, 28 Sup. Ct. Rep., 163. In the case last cited, the question was whether a false oath made in final proof required by a regulation of the Commissioner of the Land Office constituted perjury. The statute made certain requirements in regard to preliminary proofs and reiterated some of them in the section relating to final proofs, but omitted the one which, by the regulations made by the Commissioner under the power conferred by the act to give effect to its provisions, was required. It was held that the power to adopt rules and regulations for the enforcement of the act could not be construed to warrant one that was in fact an addition to the act."

From the authorities here cited it must be apparent to anyone reading them in connection with the Act here in question that the Department, in formulating this regulation, attempts to add to, alter and amend the statute.

B.

There is no Provision in the Act for Punishing a Misbranding in Violation of any Regulation Made by the Several Secretaries.

When this case was argued in the Court of Appeals, one of the points made was that Congress cannot delegate to the several secretaries the power to make regulations which regulations would impose a penal liability on the defendant in error and appellee. It is not our intention to consider that proposition here, because this court has so clearly held that there can be no such thing as a regulation of the Department punishable as a crime, unless the Act of Congress itself providing for such regulation also provides for a punishment in case of a violation thereof. And this court has so well drawn the distinction between cases where the Act defines the general scope, and permits the Secretary to make regulations as to details, and punishes a violation of those regulations, and an Act which does not provide for the punishment for the violation of any regulation, that it is not necessary to consider at all the power or authority of Congress to delegate such power to the three secretaries, because in this case no such power has been delegated, and you can read nowhere in the Act a punishment for the violation of any regulation made by the three secretaries; and not being able to read it in the act, no goods can be seized, no fines or imprisonment imposed upon anyone who violates any of the regulations made by the several secretaries. In speaking of this question in the case at bar, the Court of Appeals (37 App. D. C., 353) say:

> "Since the submission of this case, the Supreme Court of the United States has rendered a decision, the opinion in which, delivered by Mr. Justice Lamar,

clearly draws the line between these powers which may be delegated by Congress to an executive officer, and those which may not. United States vs. Grimaud, 1911, 220 U. S., 506, 55 L. ed., —, 31 Sup. Ct. Rep., 480. That was an indictment for violating a regulation of the Secretary of Agriculture relating to the use and occupancy of public forest reservations. It was said that in the nature of things it was impracticable for Congress to provide regulations for the various and varying details of the management of the forest reservations, and that it was within its power to authorize the Secretary to make such regulations as would secure the objects of such reservation, namely, to regulate the use and occupancy and preserve the forests from destruction. Having so done, it declared that 'any violation of the provisions of this act or such rules and regulations shall be punished as provided in Sec. 5388, Rev. Stat. U. S. Comp Stat., 1901, p. 3649, as amended.' The violation of such reasonable rules and regulations is 'made a crime, not by the Secretary, but by Congress. The statute, not the Secretary, fixes the penalty.' It is this feature of the act that differentiated the case from Williamson vs. United States, *supra*, and other cases cited, which, in our opinion, furnish the rule of determination for the case at bar. Congress here prescribed what the labels should contain, and conferred no power upon the Secretary to make a regulation adding anything thereto."

The statute here in question provides for no punishment for violating a regulation even though the regulation be a mere detail in the definition of a crime substantially defined by Congress. Nowhere does the Act require after the name "acetphenetidin," that we add, "a derivative of acetanilid," and nowhere does the Act provide for a punishment if we do not add after the word "acetphenetidin," the words, "a derivative of acetanilid." And nowhere in the Act does Congress provide for a punishment of any person

who violates any regulation made by the Secretary. This being so, the goods of the defendant in error and appellee cannot be seized, nor could the defendant in error and appellee be prosecuted for a violation of a regulation, the penalty for which does not appear in the statute. If Congress had desired in this Act to make the violation of a regulation a penal offense, they would have said so in the usual form that Congress uses when it attempts to make the violation of a regulation a penal offense. And the lack of such a provision in the oleomargarine act was considered by this court in the case of United States vs. Eaton 144 U. S., 677, sufficient to defeat a prosecution under the Act for a violation of a regulation. In that case the court say:

> "Much more does this principle apply to a case where it is sought substantially to prescribe a criminal offense by the regulation of a department. It is a principle of criminal law that an offense which may be the subject of criminal procedure is an act committed or omitted 'in violation of a public law, either forbidding or commanding it.' 4 American & English Encyclopedia of Law, 642; 4 Bl. Com., 5.
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> "It would be a very dangerous principle to hold that a thing prescribed by the Commissioner of Internal Revenue, as a needful regulation under the Oleomargarine Act, for carrying it into effect, could be considered as a thing 'required by law' in the carrying on or conducting of the business of a wholesale dealer in oleomargarine, in such manner as to become a criminal offense punishable under Section 18 of the Act; particularly when the same Act, in Section 5, requires a manufacturer of the article to keep such books and render such returns as the Commissioner of Internal Revenue, with the approval of the Secretary of the Treasury, may, by regulation, require, and does not impose, in that section or elsewhere in the Act, the duty

of keeping such books and rendering such returns upon a wholesale dealer in the article. * * *

"Regulations prescribed by the President and by the heads of departments, under the authority granted by Congress, may be regulations prescribed by law, so as lawfully to support acts done under them and in accordance with them, and may thus have, in a proper sense, the force of law; but it does not follow that a thing required by them is a thing so required by law as to make the neglect to do the thing a criminal offense in a citizen, where a statute does not distinctly make the neglect in question a criminal offense."

Again, in the same case, the court says:

"It is necessary that a sufficient statutory authority should exist for declaring any act or omission a criminal offense, and we do not think that the statutory authority in the present case is sufficient. If Congress intended to make it an offense for wholesale dealers in oleomargarine to omit to keep books and render returns as required by regulations to be made by the Commissioner of Internal Revenue, it would have done so distinctly in connection with an enactment such as that above recited, made in Section 41 of the Act of October 1, 1890."

In the case of United States vs. Sandfuhr, 145 Fed. Rep., 49, the court say (p. 51):

"If Congress has made a violation of this regulation a criminal offense, the indictment could be sustained. This has been the uniform ruling of the courts, and neither the learned district attorney nor the court has been able to find any statute making the violation of this regulation a criminal offense. Finally, statutes cannot be made to rest upon any presumption. As the indictment fails to charge any violation of a statute enacted by Congress, or regulation of the head of

a department, the violation of which is made punishable by any Act of Congress, the demurrer must be sustained."

In the case of Commonwealth vs. Crane, 158 Mass., 219:

"The authority given to the Commissioner of Internal Revenue to make all needful regulations for the carrying into effect of the act, does not authorize the imposition of a penalty for the violation of the regulation, *where none is imposed by the act.*"

This very question was considered by this court in the case of United States vs. Grimaud, 220 U. S., 506, where the court, in showing the distinction between a statute which imposes a penalty for the violation of a regulation and one that does not, say:

"The Secretary of Agriculture could not make rules and regulations for any and every purpose. Williamson vs. United States, 207 U. S., 462. As to those here involved, they all relate to matters clearly indicated and authorized by Congress. The subjects as to which the Secretary can regulate are defined. The lands are set apart as a forest reserve. He is required to make provision to protect them from depredations and from harmful uses. He is authorized 'to regulate the occupancy and use and to preserve the forests from destruction.' A violation of reasonable rules regulating the use and occupancy of the property is made a crime, not by the Secretary, but by Congress. *The statute, not the Secretary, fixes the penalty.*"

Again, in that case, the court say:

"The defendants rely on United States vs. Eaton, 144 U. S., 677, 36 L. ed. 591, 12 Sup. Ct. Rep., 764, where the act authorized the commissioner to make

rules for carrying the statute into effect, but imposed no penalty for failing to observe his regulations. Another section (5) required that the dealer should keep books showing certain facts, and providing that he should conduct his business under such surveillance of officers as the commissioner might by regulation require. Another section declared that if any dealer should knowingly omit to do any of the things 'required by law,' he should pay a penalty of a thousand dollars. Eaton failed to keep the books required by the regulations. But there was no charge that he omitted 'anything required by law,' unless it could be held that the books called for by the regulations were 'required by law.' The court construed the act as a whole, and proceeded on the theory that while a violation of the regulations might have been punished as an offense if Congress had so enacted, it had, in fact, made no such provision so far as concerned the particular charge then under consideration. Congress required the dealer to keep books rendering return of materials and products, but imposed no penalty for failing so to do. The commissioner went much further, and required the dealer to keep books showing oleomargarine received, from whom received, and to whom the same was sold. It was sought to punish the defendant for failing to keep the books required by the regulations. Manifestly this was putting the regulations above the statute. The court showed that when Congress enacted that a certain sort of book should be kept, the commissioner could not go further and require additional books; or, if he did make such regulation, there was no provision in the statute by which a failure to comply therewith could be punished. It said that, 'if Congress intended to make it an offense for wholesale dealers to omit to keep books and render returns required by regulations of the commissioner, it would have done so distinctly,'—implying that if it had done so distinctly, the violation of the regulations would have been an offense.

> "But the very thing which was omitted in the oleomargarine act has been distinctly done in the forest reserve act, which, in terms, provides that 'any violation of the provisions of this act or such rules and regulations (of the Secretary) shall be punished' as prescribed in No. 5388 of the Revised Statutes as amended."

Again, in Standard Oil Co. vs. United States, 222 U. S., 77, this court say:

> "As penalties which are not authorized by law may not be inflicted by judicial authority, it follows that to meet the situation with which we are confronted, the application of remedies two-fold in character becomes essential."

Again, in the case of United States vs. George, 228 U. S. 14, in this case by regulation the Secretary attempted to prescribe forms of taking pre-emption and final homestead proofs by question and answer, and provided that the claimant would be required to testify as a witness in his own behalf in the same manner. In other words, making the claimant a witness, and the statute requiring two witnesses other than the claimant really made it necessary to have three witnesses. This court say:

> "It is manifest that the regultion adds a requirement which that section does not, and which is not justified by Section 2246. To so construe the latter section is to make it confer unbounded legislative powers. What, indeed, is its limitation? If the Secretary of the Interior may add by regulations one condition, may he not add another? If he may require a witness or witnesses, in addition to what Section 229 requires, why not other conditions, and the disposition of the public lands thus be taken from the legislative branch of the government and given to the discretion of the Land Depart-

ment? It is not an adequate answer to say that the regulation must be reasonable. The power to make it is expressed in general terms. If given at all it is as broad as its subject and may vary with the occupant of the office. This is to make conditions of title, not to regulate those constituted by the statute.

"In the case of United States vs. United Verdie Copper Co., 196 U. S., 207, this court considered the power of the Secretary of the Interior under an Act of Congress giving the right to cut timber from the public lands for certain purposes, which were enumerated 'or domestic purposes,' and making the right subject to such rules and regulations as the Secretary of the Interior might prescribe 'for the protection of the timber and of the undergrowth growing on such lands, *and for other purposes.*' (Italics ours.) The Secretary made a regulation which provided, among other things, that no timber should be 'permitted to be used for smelting purposes, smelting being a separate and distinct industry from that of mining.' The justification urged for the regulation was that the word 'domestic' meant household. This court rejected the contention and decided that the regulation transcended the power of the Secretary. We said: 'If rule 7 (the regulation involved) is valid, the Secretary of the Interior has power to abridge or enlarge the statute at will. If he can define one term, he can another. If he can abridge, he can enlarge. Such power is not regulation; it is legislation.'

"In that case the power of the Secretary of the Interior was directly associated with the right conferred; yet it was held that such power could not qualify or limit the right. In other words, a distinction between the legislative and administrative function was recognized and enforced. And, similarly, this distinction must be recognized and enforced in the case at bar. The distinction is fundamental. Where the charge is of crime it must have clear legislative basis. In illustration, we may cite Williams vs. United States, 207 U. S., 425; U. S. vs. Keitel, 211 U. S., 370; United

States vs. Eaton, 144 U. S., 677; Morrill vs. Jones, 106 U. S., 466; United States vs. Biggs, 211 U. S., 507, Dwyer vs. United States, 170 Fed. Rep., 160."

The proposition is fundamental that where an offense is charged, such charge must be written within the four corners of the statute, and its punishment prescribed by the statute. You can read and reread this statute, and you fail to find any reference to a seizure of goods or punishment of any offender under the Act *by reason of the violation of any regulation that the several secretaries might make.*

This merely emphasizes what we have already said, that it was never the intention of Congress in Section 3 to attempt to give to the secretaries any authority to make a regulation, even though it be mere detail, which could be punished with penalties prescribed in the Act for violating the Act itself. If the secretaries can add to the Act and require us to tell the parent of a derivative, they could say that if hereafter there is discovered any derivative of derivative, that it is still necessary to name the parent. If they can add to the Act in regard to stating the name of a parent, then they can add to any other part of the Act; they can fix the size of the letters on the bottle, and say that unless they are printed in that size, the parties shall be punished under the Act; they can prescribe the size of cartons for drugs, and if the cartons are not of a particular size, they can say that the parties shall be punished under the Act. They might make, if the Government's contention is sustained innumerable facts, all of which would be offenses, but as this is legislation, and not regulation it is submitted that such a proposition cannot be sustained, that wherever a person can be prosecuted in a court for the violation of a regulation, the statute under which such prosecution is had must state the fact that if anyone violates any regulations

made under the statute, that the punishment for such violation shall be (as provided in the act); and you cannot proceed to attempt to punish the violation of a regulation where there is not written in the Act the penalty for the violation of such regulation.

III.

IS THE STATEMENT ON THE LABELS OF THE PACKAGES THAT NO ACETANILID IS CONTAINED THEREIN FALSE AND MISLEADING BECAUSE IT, THE SAID STATEMENT, *IMPORTS AND SIGNIFIES* THAT THERE IS NO QUANTITY OR PROPORTION OF ANY DERIVATIVE OF ACETANILID CONTAINED IN SAID DRUG?

The paragraph of the libel under which this proposition is raised is as follows:

> "Your libelant further charges that each and all of said packages of drugs are further misbranded, in that the labels thereon are false and misleading, for the reason that each and all of said labels bear the statement that no acetanilid is contained therein, and that said statement imports and signifies that there is no quantity or proportion of any derivative of acetanilid contained in said drug."

The statement that there is no acetanilid contained in said drug is absolutely true. There is no acetanilid in the substance, and there is no acetanilid in acetphenetidin, but the government claims that whenever drugs are labelled, "contains no acetanilid," it is thereby alleged that there is no quantity or proportion of acetphenetidin therein. The package alleges that there is acetphenetidin therein, but does state a truth, that is no acetanilid therein. The Government says

that no man has the right to tell the truth. It is admitted that the parent substance is not present when an article contains merely a derivative thereof, but it is insisted that to say that the parent substance is absent is misleading and signifies the absence of the derivative,—such a proposition is so fallacious that to state it is to refute it.

And here again the Government, in order to avoid what must necessarily follow, that is the holding of the court that there is nothing misleading and false in the statement, attempts to invoke the doctrine of judicial notice, and they say that acetanilid and its derivative, acetphenetidin, are kindred drugs; that they are chemically alike; that they are therapeutically alike; that they physiological effect is the same, and, therefore, to tell a person that there is no acetanilid therein is to tell him that acetphenetidin will not cure what acetanilid will; that acetphenetidin has none of the properties of acetanilid, and that acetphenetidin has none of the physiological effects of acetanilid. Just where the plaintiff in error and appellant obtains its knowledge for these propositions is unknown to us. If it were not for the fact that they devote a large part of their brief to comparing these two drugs, we would let the subject go unnoticed. There is no such issue raised here as this which is attempted to be raised. The sole issue tendered by the libel on this branch of the case is whether or not the libel is false and misleading when it says that there is no part of the parent substance contained in the drug, said statement being absolutely true. Or, putting it another way, whether or not a statement which shows that there is no part of the parent substance contained in the drug imports and signifies that there is no quantity or proportion of any derivative thereof.

A reading of the statement in the libel shows conclusively that the issue now attempted to be raised by the Government is not here in this case, and it is not here for two

reasons: (1) it is not made an issue by the pleadings; and (2) the court cannot take judicial notice of that which the plaintiff in error and appellant desires the court on this hearing to notice judicially. If issue were joined on this libel, there would be no issue as to whether or not acetanilid and acetphenetidin are similar substances. There would be no issue that acetanilid and acetphenetidin have the same therapeutical effect, nor would there be any issue that acetanilid and acetphenetidin have the same physiological effect. All of these questions are beside the issue involved. At a trial, if issue were joined on this libel, the appellant would not be permitted to prove any of the contentions that it now raises. It could not show that there was acetanilid in acetphenetidin because this, it concedes, is not the fact. Nor could plaintiff in error and appellant put on the stand any chemist to show that these two substances were in any way chemically alike, nor could it call experts on therapeutics and physiology to show that they have the same therapeutical and physiological effect. The defendant in error and appellee has been given no notice from the libel that such testimony is to be offered because there is nothing in the libel attempting to raise any such issue. But, says the plaintiff in error and appellant, while all that may be true, yet this court, on a hearing of the exceptions and objections, will take judicial notice of what is found in the encyclopedias and the dictionaries, and finding therefrom that these two substances are chemically similar, have the same therapeutical effect, and have the same physiological effect, will say (although the trial court was not asked to say, and although we were not given an opportunity to prove that such was not the fact) that all these things are true, and that, therefore, the true statement on the label that the article does not contain acetanilid is false and misleading. This is virtually an attempt to try *ex parte* the effect of these

several drugs upon the human system, something that cannot be done, something that has never been done, and something that this court will not do. If the plaintiff in error and appellant intended to raise any contentions like the ones now attempted to be raised, we should have had some notice in the libel thereof. The libel merely says that when you say a parent substance is not in a certain drug, you import and imply that there is no derivative in the said drug. For instance, if you say, labelling a bottle of vaseline, "that it contains no kerosene," you mislead people, not because there is in vaseline no kerosene, but because vaseline is a derivative of kerosene; and when you say that there is no kerosene in vaseline, you import and signify that there is no kerosene therein. But let us answer this question of judicial notice. Counsel for plaintiff in error and appellant said on argument that the authorities cited in his brief sustain his contention as to judicial notice, and that the court would take judicial notice of the chemical combination and the therapeutical and physiological effect of acetphenetidin and acetanilid.

The contention that the court would take judicial notice of the alleged intimate relation of acetphenetidin and acetanilid is not supported by the authorities cited by the plaintiff in error and appellant. The proper rule of judicial notice is as follows:

> "Courts will take judicial notice of the familiar and generally recognized principles of art and science. But the mere circumstance that facts are found in dictionaries, encyclopedias, or other books of reference will not warrant a court in taking judicial notice of them unless they are of the requisite notoriety or are so connected with facts of such nature as to partake in a sense of this characteristic." 17 A. & E. Ency. of Law, 2d Ed., 909.

In support of the definition, we refer to the case of Brown, *et al* vs. Piper, 91 U. S., 37, where this court took judicial notice of the artificial freezing of matter and held that a patent to preserve fish by freezing had no novelty.

Again, in the case of Eclipse Manufacturing Company vs. Adkins, 36 Fed. Rep., 554, 556, the court say:

> "But the court must meet each case as it arises, and in sustaining demurrers like this, keep strictly within the field of common knowledge. The practical difficulty and danger is in defining where special knowledge leaves off and common knowledge begins. The judge must always be careful to distinguish between his own special knowledge, and what he considers to be the knowledge of others in the field or sphere where the device in question is used. But, when the judge, before whom rights are claimed by virtue of a patent, can say from his own observation and experience that the patented device is in principle and mode of operation only an old and well-known device in common use, he may act upon such knowledge. The case must, however, be so plain as to leave no room for doubt, otherwise injustice may be done, and the right granted by the patent defeated, without a hearing upon the proofs. The judge must on all such questions vigilantly guard against acting upon expert or special knowledge of his own, instead of keeping strictly within the field of general or popular knowledge. While I do not intend to lay down a rule, I am free to say that I should not feel justified in holding a patent void for want of novelty on common knowledge, unless I could cite instances of common use, which would, at once, on the suggestion being made, strike persons of usual intelligence as a complete answer to the claim of such patent."

Also in Kaolatype Engraving Company vs. Hoke, 30 Fed. Rep., 444, 446:

"As the case has been presented, the question really before us is whether we will take judicial notice of certain processes described in various mechanical dictionaries, encyclopedias, and other publications produced on the hearing of the demurrer and, by reason of our taking judicial cognizance of such processes, determine that the patent in question does not describe an advance in the art to which it appertains, rising to the dignity of an invention. Besides those facts of which courts are bound by law to take judicial notice, they will ordinarily only take notice of facts of universal notoriety—of facts that are so generally understood that they may be regarded as forming part of the general knowledge of every person. Brown vs. Piper, 91 U. S., 41. The matters, of which we are asked to take judicial cognizance in this instance, and thereupon declare the invalidity of this patent, do not strike us as falling within the last category. They are a class of facts which might more properly be called to our attention on the hearing (with opportunity to the other side to rebut or explain) as tending to show the state of the art to which this patent appertains, and for the purpose of enabling us to determine whether this patent really describes a newly-discovered process which called for an exercise of the inventive faculty."

In the last case it will be noticed that the same contention is made as we make here: that this judicial notice is attempted to be invoked without opportunity on our side to rebut or explain the alleged facts desired by the plaintiff in error and appellant to be considered by the court.

From these authorities, it is submitted that this court cannot take judicial notice of the alleged facts that the plaintiff in error and appellant desires this court in this case to judicially know. It might be said that if the plaintiff in error and appellant had tendered any issue to us on these questions, we would have met it, and met it by affirmatively, showing that all of its contentions are absolutely

erroneous. Indeed, the very Pure Food Law under which plaintiff in error and appellant is proceeding meets and denies its contention that acetanilid and acetphenetidin are kindred substances. This court must take judicial notice of the United States Pharmacopœia, because Section 6 says:

> "That the term 'drug,' as used in this Act, shall include all medicines and preparations recognized in the United States Pharmacopœia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation or prevention of disease of either man or other animals."

The Pharmacopœia defines both acetanilid and acetphenetidin. Acetanilid is defined as follows:

> "The monacetyl derivative (C_6H_5 NH (CH_3.CO) of aniline."

Acetphenetidin is defined as follows:

> "Phenol derivative (Acetparaphenetidin, C_6H_4 (OC_2H_5) NH CH_3CO_1 :4), the product of the acetylization of para-amidophenetol."

The dose prescribed by the Pharmacopœia for acetanilid is four grains and the dose prescribed for acetphenetidin is 7½ grains.

As an appendix to this brief we give the printed matter of the Pharmacopœia on both acetanilid and acetphenetidin, the uses of both acetanilid and acetphenetidin as laid down in the United States Dispensatory and extracts from two Government documents, one Senate Report No. 301, and the other hearing on House Bill No. 3109, and request the court to read them in connection with the contention of

the plaintiff in error and appellant that these substances are chemically similar and alike in their therapeutical and physiological effects.

It appears from the definition in the Pharmacopœia that their chemical make-up is not alike; it appears from the documents annexed in the appendix that while the therapeutical effects are somewhat similar, the physiological effects are not the same. It appears from the Government documents that acetanilid is an adulterant of acetphenetidin, and as such is condemned not only by the published document containing the report of the health officer of the city of New York, but by Dr. Wiley himself. In fact, the Department of Agriculture itself has issued three bulletins, in which it makes comparisons between the drugs acetanilid and acetphenetidin, or as they call acetphenetidin, by its trade name "phenacetin," in all of which bulletins the Government attempts to show the greater safety of acetphenetidin.

The bulletins are "Bureau of Chemistry Bulletin No. 126," "Farmers' Bulletins Nos. 377 and 393." In Bulletin No. 126 the Department of Agriculture, after a thorough investigation, reports the relative safety of acetanilid and phenacetin as follows: To 911 cases of unfavorable results from the use of acetanilid, there are only 166 cases of unfavorable results from the use of phenacetin. To 144 cases of habitual use of acetanilid, there are 18 cases of habitual use from phenacetin.

The Department of Agriculture also found that phenacetin is regarded as the least dangerous of these drugs by 231 physicians, to 58 who considered acetanilid the least dangerous. In other words, three out of every four physicians consider phenacetin less dangerous than acetanilid, and therefore many of them prescribe Antikamnia because they know that it does not contain acetanilid.

Taking acetphenetidin and acetanilid, as the Government in the several circulars and papers in the appendix differentiates between the drugs, do not the public receive something different from acetanilid when they receive acetphenetidin? If the public know as the Department knows, the difference between these two drugs, the public would not want a drug with acetanilid in it if one could be obtained with acetphenetidin, and if there was a drug which stated that it contained acetphenetidin, the public would want to know also whether there was in it any acetanilid.

Again, it might be said to be a well-known fact that in all of these headache remedies there was a substance similar to that of anipyrine; in other words, a coal tar product of some kind. Would not the defendant in error and appellee have a right to call attention to the fact that in its remedy was the higher grade substance, the higher priced substance, the milder substance acetphenetidin, and not the cheaper substance, the stronger substance, acetanilid? People who know the difference between the two drugs will not use acetanilid when they can use acetphenetidin. Therefore, when on the labels in this case, the statement appears that it contains no acetanilid, and does contain acetphenetidin, this tells such people that the drug they object to is not in the preparation, but the drug that they desire is there. Instead of being misleading, the label tells the people what they want to know. Of course, if we would have a suppositious habitual user, such as the Department in its circulars in relation of acetanilid refers to, this statement might mislead such person if he did not know acetphenetidin was a milder coal-tar product. However, our drugs are sold for the benefit of the public, and not for the suppositious habitual user of the Department of Agriculture.

Dr. Wiley, in his hearing before the Senate Committee, states, saying phenacetin, "the genuine article," is "protected by patent."

An examination of the labelling of different kinds of drugs will disclose the fact that where the acetphenetidin is purchased from the owner of the trade-mark, they use the word "phenacetin," thus a tablet is known as "Phenacetin and Quinine," manufactured by Sharp & Dohme, of Baltimore, Maryland, "Phenacetin and Salol Gelatine Coated Pills," produced by the same manufacturer. Again we have tablets "Phenacetin and Caffeine, No. 2," produced by the same manufacturer. On the other hand, a label on a product sold by E. R. Squibb & Sons, Brooklyn, New York, reads, "100 Tablets Salol and Acetphenetidin Squibb," and on each of the packages mentioned the quantity of phenacetin and acetphenetidin is given.

We desire to reiterate that the libel itself does not allege that there is any acetanilid contained in the ingredients in any of the packages, but merely says that because acetphenetidin is contained therein, and because acetphenetidin is a derivative of acetanilid, it is false and misleading to state that there is no acetanilid contained therein. And the libel admits that there is no acetanilid in the drug here under consideration. Nor can it be contended for a moment that because the libel alleges that acetphenetidin is a derivative of acetanilid, that there is contained in any of these packages any acetanilid, and the Government admits in this case that there is in these packages no acetanilid.

Taking the definition of "derivative," whether it be the popular or chemical definition, it cannot be said for a moment that any of the parent substance is in such derivative. Webster's International Dictionary defines "derivative" (chemical definition) "A substance so related to another substance by modification or partial substitution, as to be regarded as derived from it."

"Derivative" in its popular sense is defined by the Century Dictionary, "That which is derived—that which is deduced or comes by derivation from another."

And the verb "derived" is defined (chemical definition), "To obtain one substance from another by actual or theoretical substitution. As to derive an organic acid from its corresponding hydro-carbon."

The term derived is defined in two cases as follows; Farbenfabreken of Elberfeld Company vs. U. S., and Pickhardt vs. U. S., 102 Fed. Rep., 602.

"The term 'derived from' used in the tariff Act to describe a product has its ordinary meaning of 'produced from' * * *. It is entirely well settled that, in the interpretation of the revenue laws, words are to be taken in their commonly received and popular sense."

The words in a penal statute are to be construed according to their popular definition. This was decided by this court in Sarlls vs. United States, 152 U. S., p. 574, where the court say:

> "The reasoning on which such a conclusion is reached excludes the common and popular signification of the words, and finds the meaning of the statute in the fact—true in a scientific sense that alcohol is found in fermented as well as in distilled liquors, and that the purpose of the statute is to prevent the mischief occasioned by the use of intoxicating drinks. We cannot agree with this method of reading a penal statute. The purpose of such a statute is to notify the public of the legislative intent, not to furnish scientific definitions. That intent is in most cases to be found by giving the words the meaning in which they are used in ordinary speech."

Taking the definition of "derived" in its popular sense, as this court say it should be taken, or even taking it in its chemical sense, there is nothing supporting the idea that in a derivative there is something of the parent substance. For instance, anti-pyrin and carbolic acid are produced from

a common parent substance; but it would not be contended for a moment that a person would mislead anyone, or misstate a fact, by saying that neither of these products contain part of the parent substance. Nor would it be misleading to state, referring to a preparation of anti-pyrin, that it contained no carbolic acid, nor in a statement regarding carbolic acid, that it contained no anti-pyrin. All these facts are true; and they must be admitted to be true, because they cannot be contradicted. Therefore, although we state that acetanilid and acetphenetidin are coal tar products; still it would be just as untrue to state that in acetanilid there is acetphenetidin, as to state that in acetphenetidin here is acetanilid. These substances are derived from a parent substance by reductions entirely different and distinct.

The Court of Appeals, speaking of this proposition (37 App. D. C., 354), say:

> "The second proposition is this in substance: The statement on the label that the drug 'contains no acetanilid' is false and misleading, and constitutes misbranding, within meaning of the Act. The libel does not expressly charge that acetphenetidin contains acetanilid. If it did, there would be no doubt of the soundness of the proposition, for the exceptions necessarily admit every fact plainly alleged. But it contains no such allegation. It charges that the labels are false and misleading, 'for the reason that each and all of said labels bear the statement that no acetanilid is contained therein, and that said statement imports and signifies that there is no quantity or proportion or any derivative of acetanilid contained in said drug.' It is argued in support of the proposition that acetphenetidin necessarily contains some appreciable quantity or proportion of the latter drug; and it is further argued that this is a matter of common knowledge of which the court may take notice of without proof.

We cannot agree that it is a matter of common knowledge that a chemical derivative necessarily contains, or is of the same nature as, the substance whence it may be derived. It was stated on the argument, without dissent, that very many well known substances, including acetanilid, are derivatives of benzin or benzol. Some of these derivatives are inocuous, others entirely harmless. While, therefore, acetphenetidin is a chemical derivative of acetanilid, and may be derived therefrom in practice, it is in a general sense a derivative of benzin or benzol, and may, for all that we know, be derived therefrom in actual practice for commercial use. When one wishes to ascertain the common meaning or signification of a word, resort is ordinarily had to the accredited dictionaries of the language. Marray's English Dictionary defines a chemical derivative thus: 'A compound obtained from another, *e. g.*, by partial replacement.' The definition of the Standard Dictionary is substantially the same. In the latest edition of Webster's International Dictionary the following definition is given: 'A substance so related to another substance by modification or partial substitution as to be regarded as derived from it, even when not obtainable from it in practice.' These definitions do not carry us very far. About as far as common knowledge goes is that chemical changes occur in substances through the substraction or the addition of some particular element. Sometimes the mingling of several substances having chemical affinities, but respectively inocuous, may produce a deadly poison. And sometimes the substraction of an element from a poisonous substance may produce another that is perfectly harmless. The principles that direct these combinations and control the transformations are beyond common knowledge. They can only become known through the special study of the science of chemistry.

"Whether, then, the addition or substraction of elements through which acetphenetidin may, in theory or in practice, be derived from acetanilid, produces such a chemical change of substance that it may be truly

said to contain no acetanilid, or produces a substance which still contains an appreciable quantity or proportion of the same, presents a question of fact, which, in our opinion, must be determined on the evidence of witnesses skilled in the science of chemistry.

"To authorize the introduction of evidence an issue must be raised in the pleadings.

"As before pointed out, the libel does not charge that the statement that the preparation contains no acetanilid is false by reason of the fact that acetphenetidin does contain acetanilid. It carefully confines itself to the allegation that the statement is false because it does not recite that there is no quantity or proportion of any derivative of acetanilid contained therein. This clearly limits the charge of misbranding to the failure to state that acetphenetidin is a derivative of acetanilid. This is but another form of the complaint that the regulation has been violated. It does not raise an issue of fact as to whether acetphentidin actually contains a perceptible quantity of acetanilid."

In conclusion, we desire to state that the defendant in error and appellee is a manufacturing chemist, making a large number of medicines, which medicines are prescribed by physicians and sold by druggists throughout the United States; that it has no desire to mislead or deceive anyone, and is perfectly willing that anyone shall read on its remedies "acetphenetidin," where acetphenetidin is contained; that it has no desire to conceal anything, but it does desire to inform the public that it uses a drug that was well known at the time of the passage of the Food and Drugs Act; that it uses a drug that is milder than acetanilid, and in fact free therefrom; that it uses a drug that is much dearer than acetanilid, much less harmful than acetanilid, and desires the public to know that fact. And in the light of what the Department has said of acetanilid, it is not the desire of the defendant in error and appellee, when it puts into its rem-

edies acetphenetidin, to be compelled to write "acetanilid."

For these reasons it is submitted that the court below committed no error, and that the judgment should be affirmed.

DANIEL W. BAKER,
WILTON J. LAMBERT,
Attorneys for Defendant in Error and Appellee.

APPENDIX.

I.

The Pharmacopœia of the United States of America, speaking of Acetanilide, on page 3 says:

ACETANILIDUM.
Acetanilide.

C_8H_9NO—134.09.

The monacetyl derivative [$C_6H_5NH(CH_3CO)$] of aniline.

Colorless, shining, micaceous, crystalline laminæ, or a crystalline powder; odorless, having a slightly burning taste, and permanent in the air.

Soluble in 179 parts of water and 2.5 parts of alcohol at 25° C. (77° F.); in 18 parts of boiling water, and in 0.4 part of boiling alcohol; also soluble in 12 parts of ether and 5 parts of chloroform at 25° C. (77° F.).

When heated to 113° C. (235.4° F.) Acetanilide melts, and at 295° C. (563° F.) it boils without decomposition.

Upon ignition it is consumed without leaving a weighable residue.

Solutions of Acetanilide is simple solvents are neutral to test-paper.

If 0.5 Gm. of Acetanilide be agitated with 5 Cc. of colorless sulphuric acid in a clean test-tube, it dissolves without imparting color to the liquid.

On heating 0.1 Gm. of Acetanilide with 5 Cc. of concentrated solution of potassium hydroxide (1 in 4), the characteristic odor of aniline becomes noticeable. On now adding 1 Cc. of chloroform, and again heating, the disagreeable odor of phenyl isocyanide (a poisonous product) is evolved (distinction from methyl-acetanilide or antipyrine).

On boiling 0.1 Gm. of Acetanilide for several minutes with 2 Cc. of hydrochloric acid, a clear solution results, which, when mixed with 3 Cc. of an aqueous solution of phenol (1 in 20), and afterwards with 5 Cc. of a filtered, saturated solution of chlorinated lime, acquires a brownish-

red color, becoming deep blue upon supersaturation with ammonia water.

On heating 0.1 Gm. of Acetanilide with 10 Cc. of water, filtering the solution when cold, and adding bromine T. S., drop by drop, to the filtrate, a whitish precipitate of parabromacetanilide is formed (distinction from antipyrine or acetphenetidin).

A cold saturated aqueous solution of Acetanilide added to ferric chloride T. S., should not affect the color of the latter (absence of aniline salts and various allied substances).

Average Dose.—0.250 Gm.—250 milligrammes (4 Grains).

The Pharmacopœia of the United States of America, speaking of Acetphenetidin, on page 4 says:

ACETPHENETIDINUM.

Acetphenetidin.

$C_{10}H_{13}NO_2$—177.79.

A phenol derivative (acetparaphenetidin, $C_6H_4(OC_2H_5).NH_3CO_1$:4), the product of the acetylization of paramidophenetol.

White, glistening, crystalline scales or fine crystalline powder, odorless and tasteless.

It is soluble in 925 parts of water, 12 parts of alcohol, 63 parts of ether, and 20 parts of chloroform, at 25° C. (77° F.); in 70 parts of boiling water and in 2 parts of boiling alcohol.

Heated to between 134° and 135° C. (273.2 and 275° F.) it melts, and at a higher temperature burns without leaving a weighable residue.

It dissolves without color in sulphuric acid, but if shaken with nitric acid it is colored yellow, which color persists when heated.

If 0.1 Gm. of Acetphenetidin be boiled for one minute with 1 Cc. of concentrated hydrochloric acid and the solution diluted with 10 Cc. of water, cooled and filtered, it should yield on the addition of 3 drops of an aqueous solution of chromium trioxide (1 in 30) a ruby red color.

On heating 0.1 Gm. of Acetphenetidin with 5 Cc. of a

concentrated solution of potassium hydroxide (1 in 4), the odor in aniline should not be perceptible.

If 0.1 Gm. of Acetphenetidin be boiled with 10 Cc. of water it should yield a solution which, when cooled and filtered, should not become turbid upon the addition of bromine T. S. in slight excess (absence of acetanilide).

If 0.1 Gm. of Acetphenetidin be boiled for one minute with 3 Cc. of solution of sodium hydroxide (1 in 2), the solution cooled, and then agitated with 5 Cc. of a solution of chlorinated soda, there should be produced a clear yellow liquid, and not a purplish-red or brownish-red cloudy liquid or precipitate (absence of acetanilide).

A mixture of 0.3 Gm. of Acetphenetidin with 1 Cc. of 90 per cent alcohol should not acquire a red tint when diluted with three times its volume of water and boiled with one drop of tenth-normal iodine V.s. (absence of paraphenetidin).

Average Dose.—0.500 Gm.—500 miligrammes (7½ grains).

II.

The United States Dispensatory (page 8) gives the uses of acetanilid, as well as the effect:

"USES.—The effects of acetanilide upon man are very similar to those produced by antipyrine, namely, after small doses, quietness; after very large doses, malaise, a little headache, singing in the ears, weakness, and a peculiar cyanosis, with some tendency to somnolence, mydriasis, and if there has been fever, marked fall of temperature usually accompanied by, but not dependent upon, a profuse sweat. After enormous doses complete coma and collapse have been noted. It has in rare instances caused collapse and cardiac failure, and a peculiar measles-like eruption is not very uncommon. Lake toxic doses have caused in animals and in man anesthesia, loss of reflex activity, tremors, irregular failing respiration, convulsions, coma, and general paralysis. The cyanosis is due to the formation of methæmoglobin in the blood. In the animal system acetanilide appears to break up into acetic acid and aniline, the

aniline in turn undergoing oxidation into paramidophenol, which unites with sulphuric acid to be eliminated as paramidophenol sulphate.

Death has, in a number of cases, been produced by acetanilide when used for medicinal purposes. Five grains (0.32 gm.) are alleged to have caused fatal heart failure (Ind. Med. Jour., Sept., 1890); but there have been instances of recovery after the dose of an ounce (31 Gm). Sixty grains (3.9 Gm.) have frequently been followed by serious collapse, and in some cases by death. It is also necessary to exercise some care in the external use of the drug, for various cases of severe poisoning have been reported as caused by such use.

There is a widespread but perhaps not well-grounded belief in the profession that accidents are more rare after acetanilide than after antipyrine, but the medicinal application of acetanilide seems to be identical with that of antipyrine, save only as it is modified by the insolubility of acetanilide. It is also somewhat more powerful than antipyrine, its full dose being ten grains (0.65 Gm.), repeated if necessary; preferably administered in capsules or wafers. For details of medicinal use, see *Antipyrina*. Acetanilide is germicidal, and seems to be especially active in inhibiting the growth of pathogenetic organisms. It is also analgesis, and affords a very useful dressing for wounds and ulcers. The drug itself may be used in the form of a fine powder, or an ointment may be employed in the strength of from 10 to 50 per cent. In certain mucous inflammations, as vaginitis and urethritis, a local application (20 to 40 grains to the fluid ounce) has been found very effective. Acetanalide may be given in the form of powder, suspended in mucilage of acacia and syrup, or in the form of tablets or capsules.

Dose, from five to eight grains (0.32 to 0.5 gm.)."

The United States Dispensatory (page 10) gives the uses of acetphenetidin, as well as the effect:

"USES.—Acetphenetidin was first introduced as an antipyretic by Hinsberg and Kast, who found that in order to produce toxic effects in the lower animals enormous doses

are required. These cause vomiting, staggering, hurried respiration, somnolence, cyanosis, methæmoglobinization of the blood. In man no fatal cases of poisoning have been reported, but Hollopeter saw twenty-two and a half grains produce in a woman collapse with cyanosis. Acetphenetidin would seem to be one of the safest, as it certainly is one of the most efficient drugs of its class. It is asserted that its antipyretic action is more gradual, more prolonged, and less apt to be attended with disagreeable symptoms than that of antipyrine and other allied drugs. The experiments of Ott and of Cerna and Carter appear to prove that the fall of temperature produced by acetphenetidin is due to a lessened production of animal heat caused by a direct influence of the drug upon the thermogenetic centres, and is not necessarily accompanied by any distinct alteration of the circulation. H. C. Wood, Jr. (Univ. Med. Mag., July, 1900), found that when it is given intravenously it has no effect on blood pressure, but that in enormous doses it paralyzes respiration. It seems also to be a depressant to the spinal cord. As an antipyretic and as an analgesic, acetphenetidin appears to cover in its usefulness the same range as does antipyrine. In nervous headaches the combination of it with caffeine (twelve grains to three) is often singularly advantageous. By many, acetphenetidin is believed to be less depressing than is antipyrine. Urticaria has been noted after its use, but it seems not to produce any characteristic eruption. According to Reuter, paraphenetidin, which is liable to occur in commercial phenacetin, is a dangerous poison, especially acting upon the kidneys.

Dose, from five to fifteen grains (0.32 to 1 Gm.)."

III.

58th Congress, 2d Session. SENATE. Report No. 301.

ADULTERATION OF FOODS, ETC.

January 15, 1904.—Ordered to be printed.

MR. HEYBURN, from the Committee on Manufactures, submitted the following:

REPORT.

(To accompany S. 198.)

The Committee on Manufactures, to whom was referred the bill (S. 198) for preventing the adulteration, misbranding, and imitation of foods, beverages, candies, drugs, and condiments in the District of Columbia and the Territories, and for regulating interstate traffic therein, and for other purposes, beg leave to report as follows:

* * * * * * * * *

(Page 23.)

Senator McCumber. Speaking of these samples and the percentage of adulteration therein being much greater than it probably would be if all samples were examined, I notice, under date of January 14, 1903, in the New York *Evening Post*, an article in relation to sham phenacetin, in which it is stated that of 373 samples bought from as many retail druggists in the city of New York, 315 were found to be adulterated. Many of the samples consisted of acetanilid, which is a heart depressant and very cheap. It was found to be the most common substitute. This would indicate not only that the suspected article is adulterated, but that the entire supply is largely adulterated, as shown by the New

York *Evening Post*, whose agents bought it generally and paid the high price for it. It is stated that the wholesale price of phenacetin is approximately $1 per ounce, while that of the adulterated article is about 25 cents a pound.

(Page 24.)

Doctor Wiley. That is a very peculiar case. Here is an article which is protected by patent right and is made in Germany. The patentees will not allow it to be made in this country, because by excluding it absolutely they get their own price for it. It is a trust article. Acetanilide, which is a very grave poison, has been substituted largely, because it has the same effect of curing headaches that phenacetin has; but it is very much more dangerous. Both are dangerous.

Senator McCumber. Phenacetin could be taken in very much larger quantities, if so prescribed.

Doctor Wiley. It is so much less injurious than acetanalide that there never should be any replacement. It is a fraud, a pure and simple adulteration. That would not be true of all drugs. Some kinds of drugs are very generally adulterated, while others are not adulterated at all, practically.

Perhaps the percentage might be different, but what I said in regard to the practice would be the same with respect to both. We found the same thing. We have examined that same subject in the Department of Agriculture in our drug laboratory, and we found adulterations of the same kind, but not to the same extent.

We find another adulteration, to which the makers of phenacetin are very much opposed, and that is what is called peddled phenacetin. In Canada phenacetin is worth about one-fourth as much as it is here, perhaps less than that. It is smuggled across the border—the genuine article—and sold largely in this country, contrary to law. That is a fraud on the makers, who are protected by patent.

IV.

EXTRACT FROM HEARING ON H. R. 3109, BEFORE THE COMMITTEE ON MANUFACTURES, UNITED STATES SENATE, BEING "AN ACT FOR PREVENTING THE ADULTERATION, MISBRANDING, AND IMITATION OF FOODS, BEVERAGES, CANDIES, DRUGS, AND CONDIMENTS IN THE DISTRICT OF COLUMBIA AND THE TERRITORIES, AND FOR REGULATING INTERSTATE TRAFFIC THEREIN AND FOR OTHER PURPOSES."

Tuesday, January 20, 1903—10 a.m.

Hon. P. J. McCumber, Chairman.

The Chairman. What organizations are represented by those who are present this morning?

MR. CHARLES ROOME PARMELE introduced.

The Chairman. Please state your position; what official position, if any, do you occupy?

Mr. Parmele. I am a manufacturing chemist of New York City

Mr. Chairman. What persons are here desiring hearings and what organization, if any, do they represent?

Mr. Parmele. Dr. Frank P. Foster, the author of Foster's Encyclopedic Medical Dictionary and editor New York Medical Journal; Prof. Smith Ely Jelliffe, professor in the College of Pharmacy, New York City, also editor of Medical News; Mr. William J. Evans, representing McKesson & Robbins, drug manufacturers and wholesale druggists; Edward G. Wells, representing the M. J. Breitenbach Company and the C. N. Crittenton Company; Edward M. Johnson, representing the American Ferment Company, and Samuel Owen, representing Cress and Owen Manufacturing Company. Shall I proceed, Mr. Chairman?

* * * * * * * * *

(Page 2):

Mr. Parmele. As an illustration, here is the Pharmacopœia and here is Dr. Foster's Encyclopedic Medical Dictionary—he considers this dictionary in some respects a back number—it is fairly comprehensive. Look at the two works (calling attention to the books—the Pharmacopœia, one volume, Dr. Foster's work in four volumes).

Only those who come in daily contact with this drug situation can appreciate the extent to which substitutions and adulterations exist, and if this definition as now in the bill should generally stand it would prevent action against the chief offenders, because the bulk of their dishonesty is in the handling of just those products which are now in the Pharmacopœia.

Take phenacetin, for instance. With your permission, Mr. Senator, I will read to you a report made by the president of the New York Board of Health, Dr. Ernest Lederle, to the sanitary superintendent of New York.

The Chairman. We will be glad to hear the report read.

Mr. Parmele (reads):

(Department of Health, City of New York, southwest corner Fifty-fifth Street and Sixth Avenue, Borough of Manhattan, division of chemistry.)

New York, January 10, 1903.

To the Assistant Sanitary Superintendent.

Sir: I respectfully present the following report on an examination made of samples of phenacetin powders dispensed by pharmacists in this city:

The adulteration and substitution of drugs is believed to be widespread and flagrant and is an evil which is a decided menace to life and health. In most cases such [page 3] adulteration or substitution can not readily be detected unless by chemical analysis. Not having the necessary expert chemical assistance at their command, both the physician and patient are placed at the mercy of the druggist, a situation which

is understood and taken advantage of by the unscrupulous. The fact that the victims in these cases are already in bad health makes such action all the more pernicious; not only is the patient taking medicine which in many instances is doing direct injury, but the physician is mystified by the strange action of drugs prescribed by him, when in reality his patient is taking something entirely different from the medicine called for by the prescription.

Careful inquiry elicited the information that one of the most commonly adulterated drugs and one for which cheaper substances are frequently substituted was phenacetin. This was consequently chosen as the first of a systematic investigation into the question of drug adulteration as a whole.

Phenacetin is an antipyretic so commonly used that it may practically be considered a household remedy, and is almost universally dispensed by druggists over the counter without a physician's prescription. The usual dose is from five to ten grains.

The wholesale price of phenacetin is approximately $1 per ounce, while that of its usual adulterant or substitute, acetanilid, is about 25 cents per pound. The financial inducement to substitute is consequently great.

As will be seen by the results obtained in this laboratory, however, acetanilid is not the only adulterant in use.

The samples examined were collected with the assistance of the division of inspections. In all, 373 samples were analyzed, collected in the boroughs of Manhattan and Brooklyn. Of these, 58 were pure phenacetin as labeled, 315 were adulterated or were cases of substitution.

Of the adulterated samples 267 were mixtures of phenacetin and acetanilid, 2 were mixtures of phenacetin and sugar, 4 were mixtures of phenacetin and starch, 32 were pure acetanilid, 4 were mixtures of acetanilid and cane sugar, 1 was a mixture of acetanilid and milk sugar, 3 were mixtures of acetanilid and starch, 1 was antipyrin, 1 was quinine sulphate.

Adulterated samples were purchased by inspectors of this department at the following pharmacies:

The names were not deemed necessary and therefore omitted.

The prices paid by the inspectors for three 10-grain powders varied between 15 and 30 cents. A fair average would be 20 cents. If pure phenacetin is sold at this price, an ounce, costing $1, is sold for $3.20, a profit of over 200 per cent. Such a profit, however, does not appear to be sufficient. Acetanilid, costing about 2½ cents per ounce, is substituted and sold at the same price as pure phenacetin.

No valid excuse can be made for this form of dishonesty. The claim can not even fairly be made that in some cases the druggist himself is the innocent victim of a fraud, for the reason generally given to justify the enormous percentage of profit charged by pharmacists is that the charge is made for the skill and special knowledge required in dispensing drugs and not for the intrinsic value of the drug sold. This appears to be a fair claim, but then, not to apply this special knowledge, while charging for it would be a fraud in itself. Moreover, ignorance and carelessness in dispensing drugs is, if anything, more dangerous to the public than deliberate dishonesty.

I want to enlarge upon one point: there were in all 373 samples of analyzed products—mark you, Mr. Chairman—53 were pure phenacetin as labeled, 315 were adulterated or were substitutions—nearly six times as many substitutions as originals.

IN THE

Supreme Court of the United States

No. 118.

UNITED STATES OF AMERICA, *Plaintiff in Error and Appellant,*

vs.

ANTIKAMNIA CHEMICAL COMPANY, *Defendant in Error and Appellee.*

ADDITIONAL BRIEF.

FOOD AND DRUG REGULATIONS.
FOOD AND DRUG ACT OF JUNE 30, 1906.

DANIEL W. BAKER,
WILTON J. LAMBERT,
Attorneys for Defendant in Error and Appellee.

PRESS OF BYRON S. ADAMS, WASHINGTON, D. C.

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No. 118.

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ADDITIONAL BRIEF.

In addition to the brief already filed, counsel desire to call the Court's attention to the fact that an examination of the copies of judgment as filed by the Agricultural Department up to February 1, 1913, numbered two thousand, three hundred and fifty (2350) will show that in no one of these cases, except the instant case, does the libel, indictment, or information charge a violation of a *rule or regulation of the Department.*

In the reported case No. 438, United States vs. Joseph J. Bishof, filed May 13, 1910, in the Police Court of the District of Columbia, and referred to in the argument as

the Ice Cream Case, the information there charged a violation of the law in the adulteration of a substance which the defendant called ice cream. The information charged that it was an imitation of ice cream and did not mention by name any regulation of the department.

We are advised that in some of the cases the regulations have been used to prove a matter of fact as to quality, etc., but that in no case reported have the regulations been treated as laying down a rule of law. The courts that have held the regulations of use prove a fact, hold them valid not under the Pure Food Act, but under Act of Congress, March 3, 1903, referred to hereafter.

In the case of the United States of America vs. Five Cases of a Liquid Food, known as "Hurdle Brand Holland Gin," District Court 807, decided December 1, 1913, by Mr. Justice Gould, holding District Court, Supreme Court of the District of Columbia (Vol. 41, Washington Law Reporter, p. 785), the defendant relied upon the regulations of the Department and claimed that his label came within Regulation 19. The Government contended that it violated that part of the regulation which reads as follows:

> "(c) The use of a geographical name in connection with a food or drug product will not be deemed a misbranding when by reason of long usage it has come to represent a generic term, and is used to indicate a *style, type* or *brand.*"

The Government contended that after the words, "Hurdle Brand Holland" there should have been inserted the word "style" or "type" before the word "Gin." The libel charged, however, a violation of the law and ***not a violation of any regulation.*** The court held that under the law the label was sufficient and dismissed the libel. Speaking of the contention of the Government, the court said:

"It was contended on behalf of the libelant that, admitting that 'Holland' as applied to a gin, has come to be a generic term; and admitting further that the label fairly states the place where the article is manufactured, yet the claimant should qualify his label by adding the word 'Domestic' type, style or process, in juxtaposition to the words 'Holland Gin.' Two answers to this contention suggest themselves. First: If 'Holland' has become generic, and if the gin distilled by the claimant contains exactly the same ingredients and is made by the same process, and is, in essence, the same identical thing as gin distilled in Holland, then it is 'Holland' gin and not 'Holland' 'type,' 'style,' or 'process.' In other words, it is entitled to be called what it is. Second: On the broader question as to whether the label as used is liable to deceive a purchaser into believing he is buying an imported article, it is rather difficult to understand how a customer who would fail to observe the words 'Distilled by Baird Daniels Co., Warehouse Point, Conn.,' plainly printed on the label, would be more liable to notice the word 'style', or 'type' or other similar word, used in connection with the words 'Holland Gin.'"

Indeed, the Department of Agriculture, through the United States Attorneys in the courts, makes no claim that they have a right to make under the Pure Food and Drugs Act, rules and regulations establishing standards. They do claim that right by virtue of the Act of Congress, March 3, 1903; in the appropriation act of that year for the Department of Agriculture, a sum of money was appropriated to the Department for the fiscal year ending June 30, 1909, for the purpose, among other things, "To enable the Secretary of Agriculture in collaboration with the Association of Official Agricultural Chemists and such other experts as he may deem necessary to establish standards of purity for food products and to determine what are regarded as adul-

terations therein for the guidance of the officials of the various States and the courts of justice."

This statute has been before the court on various occasions, some of the decisions holding the power given valid, others that it is void.

In the case of the United States vs. Frank, *et al.*, 189 Fed. Rep., 195, Hollister, District Judge, held a regulation establishing the standard of purity for certain foods valid, but he treated the standard, made by the regulation, as a fact and not as a law, and he held an information valid, which alleged a misbranding under the Food and Drugs Act itself, where the food did not come up to the standard prescribed. The defendant having pleaded guilty and counsel appearing to urge the invalidity of the regulations against the payment of a fine, the court after holding the regulation as *establishing a fact and not a law*, said that the question was really not before him on the plea of guilty.

The same question was considered in the case of United States vs. St. Louis Coffee and Spice Mills, 189 Fed. Rep., 191, and the court in that case sustained the demurrer to the information on the ground that the mere allegation that the food did not come up to the standard prescribed by the Secretary of Agriculture was not in law an adulteration under the Food and Drugs Act.

And they held that Circular 19, which was made in pursuance of the Act of March 3, 1903, cannot be considered in determining what constituted an offense of adulteration in violation of the Act of June 30, 1906.

In the case of Coopersville Co-operative Creamery Company vs. Lemon, 163 Fed. Rep., 145, the case relied upon by the Government to sustain their contention, the court, referring to the regulation there, said:

> (1) But, if not conclusive in a contested case, the regulation was at least a working regulation and guide,

enabling the officials charged with the enforcement of the law to act with impartiality and uniformity in exacting the tax imposed. Its promulgation was at least an assurance to people engaged in butter making that the administrative officials charged with the collection of this tax would not subject them to the tax or a departmental regulation of their business if their butter did not contain as much as 16 per cent of moisture, and a warning against any greater percentage. This much must be conceded. Assuming then, that it may not have the force of law as a conclusive determination of the question, does it follow, if the tentative or *prima facie* determination of the Commissioner by such a regulation is challenged by a manufacturer from whom the tax is exacted, that the act is to fail because in such circumstances there can be no final determination of the fact of what is abnormal moisture in butter? It may be that such a question, involving as it does more or less of scientific knowledge and a wide acquaintance with the moisture content of standard butter, could be more satisfactorily determined by a commission of experts or by the action of Congress itself. But does it follow that such a question could not be submitted to a jury when the enforcement of the tax is involved and the maker of butter contests the fact of an abnormal moisture content? That juries might disagree with one another as to a normal water content, and so some would be compelled to pay and others escape, may be conceded. But is not this so with respect to many questions which for centuries have gone to the jury? By what standard is a question of fraud to be tried? What is the definite fixed standard of care by which juries are to determine negligence? We tell them the care of the average prudent man is the standard. But can that be said to afford an identical idea to the mind of every juror? Questions of motive and intent are questions for the jury. Questions involving scientific knowledge far beyond that of the best class of jurymen are submitted, although the verdict may afford no standard for another case and questions depending on

science are peculiarly capable of an exact and uniform answer. Manifestly this objection is not maintainable, unless it be that as an excise tax it will lack that uniformity of operation required by the Constitution, because the verdict of one jury will afford no standard for another. But it is the peculiar province of a jury to determine disputed questions of fact. The question as to what is an abnormal moisture content in dairy butter is nothing more or less than a question of fact. If the fact exist by confession or by the determination of a jury, the butter is subject to the tax. If the fact is not in some way established, the butter is not taxable. To reply that, because all juries may not agree that a particular moisture content is essential to constitute abnormal moisture, therefore the law will lack in that uniformity essential to an excise tax, is to say that constitutional uniformity in a tax is dependent upon its intrinsic uniformity—upon its genuine equality of burden."

In the case of United States vs. 11,150 Pounds of Butter, 195 Fed. Rep., 665, 666, 667, the Circuit Court of Appeals, speaking through Sanford, Circuit Judge, came to the opposite conclusion from the opinion in 163 Fed. Rep. The court say:

"The definition of offenses, the classification of offenders, and the prescription of the punishment they shall suffer, are legislative, and neither executive nor judicial, functions. And forfeitures, fines, and penalties may not be prescribed, imposed, or inflicted for violations of a regulation of an executive department without previous legislative prescription. United States vs. Eaton, 144 U. S., 677, 688, 12 Sup. Ct., 764, 36 L. Ed., 591; United States vs. Grimaud, 220 U. S., 506, 517, 519, 522, 31 Sup. Ct., 480, 55 L. Ed., 563; St. Louis Merchants' Bridge Terminal Ry. Co. vs. United States, 188 Fed., 191, 195, 110 C. C. A., 63; United States vs. Keitel (D. C.), 157 Fed., 396, 401;

United States vs. Three Barrels of Whiskey (C. C.), 77 Fed., 963, 964.

In United States vs. Two Hundred Barrels of Whiskey, 95 U. S., 571, 573, 24 L. Ed., 491, the act there under consideration required the rectifier to do, and to refrain from doing certain specified things, empowered the Commissioner of Internal Revenue to make rules TO ENFORCE IT, AND PRESCRIBED FORFEITURES AND PENALTIES FOR THE FAILURE OF THE RECTIFIER TO DO ANY OF THE THINGS BY LAW REQUIRED TO BE DONE BY HIM, and for the doing by him of any of the things prohibited by the act. The Secretary thereupon made a regulation imposing upon rectifiers a requirement in excess of those made by the statute relative to the gauging, inspecting, and stamping of packages of distilled spirits, and a libel was filed to forfeit the whiskey there in question for a violation of the law, because this regulation was not complied with. The suit failed. The Supreme Court said:

> 'The rules and regulations which the Commissioner of Internal Revenue is authorized by Section 2 to prescribe cannot have the effect of bringing the case under the operation of the penalty provided in Section 96, if it was already covered by section 57 (Act July 20, 1868, c. 186, 15 Stat., 125, 149, 164). The regulation of the department cannot have the effect of amending the law. They may aid in carrying the law as it exists into execution, but they cannot change its positive provisions.'

In Morrill vs. Jones, 106 U. S., 466, 1 Sup. Ct., 423, 27 L. Ed., 267, the statutes provided that animals specially imported for breeding purposes should be admitted free of duty 'upon proof thereof satisfactory to the Secretary of the Treasury, under such regulations as he may prescribe.' He prescribed a regulation that animals of superior stock adapted to improving

the breed in the United States, and those only, should be admitted free under the law. The Supreme Court said:

> 'The Secretary of the Treasury cannot, by his regulations, alter or amend a revenue law. All he can do is to regulate the mode of proceeding to carry into effect what Congress has enacted. In the present case we are entirely satisfied the regulation acted upon by the collector was in excess of the power of the Secretary.'

In United States vs. Eaton, 144 U. S., 677, 687, 688, 12 Sup. Ct., 764, 36 L. Ed., 591, the defendant was indicted for a violation of the Oleomargarine Act of August 2, 1886, c. 840, 24 Stat., 209, in that he had failed to keep a book and make a monthly return showing certain matters required by regulation of the Commissioner of Internal Revenue, but not called for by the act itself. The statute required certain books to be kept, but did not specifically require a book to be kept and a monthly return to be made showing the specific matters prescribed by this regulation. This act, however, expressedly required the defendant to conduct his business under such surveillance of officers and agents as the Commissioner, with the approval of the Secretary, might by regulation prescribe, authorized the Commissioner to make rules for carrying the act into effect, and by Section 18 prescribed punishment by forfeiture and fine for the doing by any manufacturer or dealer of any act prohibited by the statute, and for his failure to do anything required by law in the carrying on or conducting of his business. The Supreme Court held that these provisions of Section 18 did not make a criminal offense as a neglect to do a thing required by law, of a neglect to do a thing required only by this regulation of the Commissioner, that the principle underlying the decision in Morrill vs. Jones applied with still greater force than in that case where, as in the Eaton case, 144 U. S.,

687, 12 Sup. Ct., 764, 36 L. Ed., 591, an attempt was made in effect to punish a crime by a regulation of a department, and that where the act of Congress did not distinctly make the violation of such a regulation a criminal offense, fines and forfeitures could not be imposed or enforced therefor.

In United States vs. Grimaud, 220 U. S., 506, 31 Sup. Ct., 480, 55 L. Ed., 563, the defendant was indicted for grazing sheep on a forest reservation without a permit, in violation of a regulation made by the Secretary of Agriculture requiring such a permit, save in cases expressly excepted by the rule. The Act of Congress, June 4, 1897, c. 2, 30 Stat., 35, expressly provided that:

> 'He (the Secretary) may make such rules and regulations and establish such service as will insure the objects of such reservation, namely, to regulate their occupancy and use and to preserve the forests thereon, and any violation of the provisions of the act, or such rules and regulations, shall be punished as prescribed in Revised Statutes, Section 5388 (U. S. Comp. St., 1901, p. 3469) as amended, which provide punishment by a fine and imprisonment.'

The Supreme Court carefully and approvingly reviewed its former opinion in Eaton's case, declared that the very thing which was omitted in the Oleamargarine Act has been distinctly done in the Forest Reserve Act, which in terms provides that 'any violation of the provisions of this act, or such rules and regulations of the Secretary shall be punished as prescribed in Section 5388 of the Revised Statutes, as amended' (220 U. S., 519, 31 Sup. Ct., 484, 55 L. Ed., 563), and held that the regulation was clearly authorized, that its violation was made criminal and the punishment therefor was prescribed by act of Congress and not by the Commissioner, and it accordingly sustained the prescription.

Here is a vital distinction between the Grimaud case, on the one hand, and the Eaton case and the case now under consideration, on the other. In the former the violation of the regulation was made criminal and the punishment therefor was prescribed by act of Congress. In the Eaton case and in this case the violation of the regulation was not made criminal, nor was the punishment therefor prescribed by any legislative action, and it is plain from the opinion in the Grimaud case that the prosecution in that suit would not have been sustained had there been no congressional prescription of the penalty for a violation of the regulation there in question.

After these decisions had been rendered, and after they had been carefully considered by this Court, it decided the case of St. Louis Merchants' Bridge Terminal Ry. Co. vs. United States, 188 Fed., 191, 194, 196, 110 C. C. A., 63m, and in that decision Mr. Justice Van Devanter, who had just taken part in the decision in the Grimaud case, participated, and he concurred in the opinion. In that case the Act of March 3, 1905, c. 1496, 33 Stat., 1264 (U. S. Comp. St. Supp., 1911, p. 1351), authorized the Secretary of Agriculture to make regulations to govern the inspection and shipment of cattle and other live stock from a quarantined State, and from the quarantined portion of any State into any other State, provided that such stock might be moved from a quarantined region in compliance with such regulations, but that it should be unlawful for any railroad company to remove from any quarantined region into another State such stock in any other manner or method, or under other conditions than those prescribed by the Secretary, and that any railroad company that violated these provisions should be punished by fine or imprisonment, or both. The Secretary made a regulation governing the transfer of such stock from one railroad company to another after it had passed out of the quarantined region into another State, and the defendant was convicted of violating that regulation. The class of railroad companies and

the class of acts punishable by the terms of the statute were railroad companies receiving stock in and transporting it from a quarantined region in one State into another State, and acts done in the course of such receipt and transportation. The effect of the regulation was to add to these classes and to bring under the penalties of the statute other railroad companies receiving the stock outside the quarantined region and other acts done outside that region, and this court held that in so far as it had that effect it was unauthorized and void."

In the case of St. Louis Merchants' Bridge Company vs. United States, 188 Fed. Rep., 191, the Circuit Court of Appeals, consisting of Judges Sanborn and Van Devanter (now Mr. Justice Van Devanter), Circuit Judges, and Reed, District Judge, Judge Sanford, in an elaborate opinion considers the whole question and comes to the conclusion that the offense must be charged in the Act and that you cannot create the offense by a regulation. The court say:

"A legislative body may delegate the power to find some fact or situation on which the operation of a law is conditioned, or to make and enforce regulations for the execution of a statute according to its terms. Union Bridge Co. vs. United States, 304 U. S., 364, 386, 27 Sup. Ct., 367, 51 L. Ed., 523; Marshall Field & Co. vs. Clark, 143 U. S., 649, 677, 693, 694, 12 Sup. Ct., 495, 36 L. Ed., 294; Caha vs. United States, 152 U. S., 211, 218, 219, 14 Sup. Ct., 513, 38 L. Ed., 415; St. Louis & I. M. Ry. vs. Taylor, 210 U. S., 281, 287, 28 Sup. Ct., 616, 52 L. Ed., 1061; Coopersville Co-operative Creamery Company vs. Lemon, 163 Fed., 145, 147, 89 C. C. A., 595.

But it cannot delegate its legislative power, its power to exercise the indispensable discretion to make, to add to, to take from, or to modify the law. 'The

true distinction,' said Judge Ranney for the Supreme Court of Ohio in Cincinnati, Wilmington & Zanesville R. R. Co. vs. Commissioners, 1 Ohio St., 77, 88, in a declaration which has been repeatedly approved by the Supreme Court, 'is between the delegation of power to make the law, which necessarily involves a discretion as to what it shall be, and conferring authority or discretion as to its execution, to be exercised under and in pursuance of the law. The first cannot be done. To the latter no valid objection can be made.' Marshal Field & Co. vs. Clark, 143 U. S., 649, 693, 12 Sup. Ct., 495, 36 L. Ed., 294; Union Bridge Co. vs. United States, 204 U. S., 364, 382, 27 Sup. Ct., 367, 51 L. Ed., 523; Morrill vs. Jones, 106 U. S., 466, 467, 1 Sup. Ct., 423, 27 L. Ed., 267; United States vs. Eaton, 144 U. S., 677, 687, 688, 12 Sup. Ct., 764, 36 L. Ed., 591; United States vs. Maid (D. C.), 116 Fed., 650; United States vs. Blaslingame (D. C.), 116 Fed., 654; United States vs. Hoover (D. C.), 133 Fed., 950, 952; United States vs. Moody (D. C.), 164 Fed., 269, 271; Locke's Appeal, 72 Pa., 491, 498, 13 Am. Rep., 716.

The attempt of the Secretary of Agriculture to add by his regulations to the class of railroad companies and to the acts punishable under the quarantine act of March 3, 1905, other railroad companies and other acts was unauthorized and ineffective. No offense was charged in the information or proved against the defendant below, the judgment is reversed, and the case is remanded to the court below, with directions to sustain the demurrer to the information and discharge the terminal company."

The admission of the Solicitor General that there can not be a prosecution without this regulation is an admission that there can not be an offense without this regulation, and therefore the regulation adds something to the statute that is not there. The regulation does not find a fact as a condition precedent to the enforcement of the statute.

Counsel have carefully considered the case of McDermott vs. State of Wisconsin, 228 U. S., 115, and in that case the court disclaims any intention of considering the validity of the regulation. The court says:

> "Whether the Secretaries had the power under the Food and Drugs Act to make the regulation set out above is not now before us. It is enough for the present purpose to say that, so far as this record discloses, it was undertaken in good faith to label the articles in compliance with the Act of Congress, and if they were not so labeled, by Section 2 provision is made for the enforcement of the Act by criminal prosecution and by Section 10 by proceedings *in rem*."

From these authorities and from the fact that in the number of cases prosecuted or attempted to be prosecuted, in only one of them (this case) they have attempted to rely upon the regulations, it is respectfully submitted that these regulations have no force of law but are merely rules laid down by the Department for the administration of the law. An examination of the regulations will show that it is not intended by the Department that they shall have the force of law but for more as a warning to manufacturers that unless they comply therewith a prosecution will be had under the law. This is well illustrated on pages 6 and 7 of the Regulations. For instance, Regulation 15 respecting the wholesomeness of colors, preservatives and other substances which are added to foods, says:

> "The Secretary of Agriculture shall determine from chemical or other examination which are permitted or inhibited in food products; and such findings shall become a part of these regulations."

It could not be said that finding of this character could have the force of law. Again on page 7 (c) and (d) in

regard to benzoate of soda mixed with food, the regulation states as follows:

> "It is not deleterious or poisonous and that no objection will be raised under the Food and Drugs Act to its use provided each container or package of such food is plainly labeled to show the presence and amount of benzoate of soda."

It surely could not be said that if a person had no such label that he could be prosecuted under these regulations when the law requires no such label. (d) refers to saccharin and permits its use until a certain date. The regulations say:

> "The Secretary of Agriculture will regard as adulterated under the Food and Drugs Act foods containing saccharin which, on or after April 1, 1912, are manufactured or offered for sale in the District of Columbia or Territories or shipped in interstate or foreign commerce."

Thus we would have the anomaly of a thing not becoming a crime until a certain date fixed by regulation. Of course this regulation only notifies persons if after that date saccharin appear in any foods, the Department will prosecute under the law, not under the regulation, and it will be for the courts to say whether the prosecution will lie under the law.

In regard to what was said about the character of the labels, the Department has no right to require any particular form or kind of label, nor, on the other hand, has a person a right to use any kind of label that would mislead or deceive. The reported cases show several instances where a foreign name has been placed on a domestic product and the

court held not that this violated a regulation, but that it violated the law itself.

The question has been asked what is the object of the regulations? This court has decided that a United States District Attorney must proceed upon the order of the Secretary of Agriculture, that such order is mandatory and therefore the Secretary of Agriculture together with the other Secretaries have laid down a chart in which they say persons shall proceed in a certain way, and unless they do so that they shall be liable to prosecution, but not prosecution under the chart, but under the law itself, and a reading of the whole of the regulations which are here incorporated will show that fact.

Regulation 28, the one under consideration in this cause, appears on pp. 11, 12 and 13 of the circular, attached to this brief, and Section 8 of the Food and Drugs Act appears on page 20.

It is respectfully submitted that these regulations in no sense have the force of law, that the most that might be said about any of them is that they form a rule of conduct, which if not followed will place a person in a position where the Secretary will order the District Attorney to proceed under the law to prosecute for a violation of the law.

Respectfully submitted,

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Issued April 10, 1913.

United States Department of Agriculture,

OFFICE OF THE SECRETARY—Circular No. 21, Seventh Revision.

(Including two acts [Public—No. 301, H. R. 11877, and Public—No. 419, H. R. 22526] to amend section 8 of the food and drugs act and Regulations 3, 5, 17 and 19, 28, and 34 as amended by F. I. D. 79, 130, 84, 112, and 93, issued October 16, 1907, February 6, 1911, February 10, 1908, January 27, 1910, and May 23, 1908, respectively; also Regulation 9, section b, as amended by F. I. D. 99, December 8, 1908, to take effect January 1, 1909, and Regulation 15 as amended to accord with F. I. D. 104, 135, 138 and 142.)

RULES AND REGULATIONS FOR THE ENFORCEMENT OF THE FOOD AND DRUGS ACT.

INTRODUCTION.

Under date of October 17, 1906, forty rules and regulations for the enforcement of the food and drugs act, June 30, 1906, were adopted by the three Secretaries. Since that date eight regulations, Nos. 3, 5, 9, 15, 17, 19, 28, and 34, have been amended, the first named by F. I. D. 79, "Collection of Samples," approved by Secretary Wilson of the Department of Agriculture, Secretary Cortelyou of the Treasury Department, and Secretary Straus of the Department of Commerce and Labor, No. 5 by F. I. D. 130, "Amendment to Regulation 5, Hearings," No. 9 by F. I. D. 99, "Change in Form of Guaranty Legend," No. 15 to accord with F. I. D. 104 on Benzoate of Soda and Nos. 135, 138, and 142 on Saccharin, Nos. 17 and 19 by F. I. D. 84, "Label" and "Character of Name," No. 28 by F. I. D. 112, on "Labeling of Derivatives," and No. 34 by F. I. D. 93, "Denaturing," all over the signatures of the Secretaries of Agriculture, the Treasury, and Commerce and Labor, with the exception of F. I. D. 142, from which the Secretary of the Treasury dissented.

Regulation 2, Original Unbroken Package, has been interpreted by F. I. D. 86, and Regulation 9, Form of Guaranty, by F. I. D. 83, the latter an opinion rendered by the Attorney General on the issue of a guaranty based upon a guaranty.

In accordance with Regulation 15, Wholesomeness of Colors and Preservatives, F. I. D. 76, on Dyes, Chemicals, and Preservatives in Foods, F. I. D. 89, Relating to the Use in Foods of Benzoate of Soda and Sulphur Dioxid, F. I. D. 92, on the Use of Copper Salts, and F. I. D. 102, amending F. I. D. 92, have been issued over the signatures of the three Secretaries, constituting decisions on these points pending the completion of investigations and the issuance of final regulations governing the use of such substances. F. I. D. 104 constitutes the final decision on the use of benzoate of soda in foods, and allows such use; F. I. D. 135, 138, and 142 constitute the final decision on the use of saccharin in food and prohibit such use after April 1, 1912.

With the exception of these amendments and amplifications the regulations as originally issued remain unchanged, and no additional rules have been adopted, the revision issued under this date incorporating the changes enumerated, together with the amendments to section 8 of the food and drugs act.

D. F. HOUSTON, *Secretary of Agriculture.*

WASHINGTON, D. C., *March 24, 1913.*

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RULES AND REGULATIONS AS AMENDED.

GENERAL.

Regulation 1. Short Title of the Act.

The act, "For preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes," approved June 30, 1906, shall be known and referred to as "The Food and Drugs Act, June 30, 1906."

Regulation 2. Original Unbroken Package.

[See also F. I. D. 86 for interpretation of this regulation.]

(Section 2.)

The term "original unbroken package" as used in this act is the original package, carton, case, can, box, barrel, bottle, phial, or other receptacle put up by the manufacturer, to which the label is attached, or which may be suitable for the attachment of a label, making one complete package of the food or drug article. The original package contemplated includes both the wholesale and the retail package.

Regulation 3. Collection of Samples.

[As amended by F. I. D. 79, October 8, 1907, to take effect November 1, 1907.]

(Section 4.)

Samples of unbroken packages shall be collected only by authorized agents of the Department of Agriculture, or by the health, food, or drug officer of any State, Territory, or the District of Columbia, when commissioned by the Secretary of Agriculture for this purpose.

Samples may be purchased in the open market, and, if in bulk, the marks, brands, or tags upon the package, carton, container, wrapper, or accompanying printed or written matter shall be noted. The collector shall also note the names of the vendor and agent through whom the sale was actually made, together with the date of the purchase. The collectors shall purchase representative samples.

A sample taken from bulk goods shall be divided into three parts, and each shall be labeled with the identifying marks.

If a package be less than 4 pounds, or in volume less than 2 quarts, three packages shall be purchased, when practicable, and the marks and tags upon each noted as above. When three samples are purchased, one sample shall be delivered to the Bureau of Chemistry or to such chemist or examiner as may be designated by the Secretary of Agriculture; the second and third samples shall be held under seal by the Secretary of Agriculture, who, upon request, shall deliver one of such samples to the party from whom purchased or to the party guaranteeing such merchandise.

When it is impracticable to collect three samples, or to divide the sample or samples, the order of delivery outlined above shall obtain, and in case there is a second sample the Secretary of Agriculture may, at his discretion, deliver such sample to parties interested.

All samples shall be sealed by the collector with a seal provided for the purpose.

Regulation 4. Methods of Analysis.

(Section 4.)

Unless otherwise directed by the Secretary of Agriculture, the methods of analysis employed shall be those prescribed by the Association of Official Agricultural Chemists and the United States Pharmacopœia.

Regulation 5. Hearings.

[As amended by F. I. D. 130, January 18, 1911.]

(Section 4.)

(*a*) When the examination or analysis shows that samples are adulterated or misbranded within the meaning of this act notice of that fact shall be given in every case to the party or parties against whom prosecution lies under this act for the shipment or manufacture or sale of the particular product and such other interested parties as the Secretary of Agriculture may direct, and a date shall be fixed at which such party or parties may be heard before the Secretary of Agriculture or such other person as he may direct. The hearings shall be had at places designated by the Secretary of Agriculture most convenient for all parties concerned. These hearings shall be private and confined to questions of fact. The parties interested therein may appear in person or by attorney and may submit oral or written evidence to show any fault or error in the findings of the analyst or examiner. Interested parties may present proper interrogatories to analysts, to be submitted to and propounded by the Secretary of Agriculture or the officer conducting the hearing. Such privilege, however, shall not include the right of cross-examination. The Secretary of Agriculture may order a reexamination of the sample or have new samples drawn for further examination.

(*b*) If, after hearings held, it appears that a violation of the act has been committed, the Secretary of Agriculture shall give notice to the proper United States attorney.

(*c*) Any health, food, or drug officer or agent of any State, Territory, or the District of Columbia who shall obtain satisfactory evidence of any violation of the Food and Drugs Act, June 30, 1906, as provided by section 5 thereof, shall first submit the same to the Secretary of Agriculture in order that he may give notice and fix dates for hearings to the proper parties.

Regulation 6. Publication.

(Section 4.)

(*a*) When a judgment of the court shall have been rendered there may be a publication of the findings of the examiner or analyst, together with the findings of the court.

(*b*) This publication may be made in the form of circulars, notices, or bulletins, as the Secretary of Agriculture may direct, not less than thirty days after judgment.

(*c*) If an appeal be taken from the judgment of the court before such publication, notice of the appeal shall accompany the publication.

Regulation 7. Standards for Drugs.

(Section 7.)

(*a*) A drug bearing a name recognized in the United States Pharmacopœia or National Formulary, without any further statement respecting its character, shall be required to conform in strength, quality, and purity to the standards prescribed or indicated for a drug of the same name recognized in the United States Pharmacopœia or National Formulary, official at the time.

(*b*) A drug bearing a name recognized in the United States Pharmacopœia or National Formulary, and branded to show a different standard of strength, quality, or purity, shall not be regarded as adulterated if it conforms to its declared standard.

Regulation 8. Formulas—Proprietary Foods.

(Section 8, last paragraph.)

(*a*) Manufacturers of proprietary foods are only required to state upon the label the names and percentages of the materials used, in so far as the Secretary of Agriculture may find this to be necessary to secure freedom from adulteration and misbranding.

(*b*) The factories in which proprietary foods are made shall be open at all reasonable times to the inspection provided for in Regulation 16.

Regulation 9. Form of Guaranty.

[As amended December 8, 1908, by F. I. D. 99, to take effect on January 1, 1909; see also F. I. D. 83 for opinion of the Attorney-General on the issue of a guaranty based upon a former guaranty.]

(Section 9.)

(*a*) No dealer in food or drug products will be liable to prosecution if he can establish that the goods were sold under a guaranty by the wholesaler, manufacturer, jobber, dealer, or other party residing in the United States from whom purchased.

(*b*) A general guaranty may be filed with the Secretary of Agriculture by the manufacturer or dealer and be given a serial number,

which number shall appear on each and every package of goods sold under such guaranty with the words "Guaranteed by [insert name of guarantor] under the food and drugs act, June 30, 1906."

(*c*) The following form of guaranty is suggested:

I (we) the undersigned do hereby guarantee that the articles of foods or drugs manufactured, packed, distributed, or sold by me (us) [specifying the same as fully as possible] are not adulterated or misbranded within the meaning of the food and drugs act, June 30, 1906.

(Signed in ink.)

—— ——.

[Name and place of business of wholesaler, dealer, manufacturer, jobber, or other party.]

(*d*) If the guaranty be not filed with the Secretary of Agriculture as above, it should identify and be attached to the bill of sale, invoice, bill of lading, or other schedule giving the names and quantities of the articles sold.

ADULTERATION.

Regulation 10. Confectionery.

(Section 7.)

(*a*) Mineral substances of all kinds (except as provided in Regulation 15) are specifically forbidden in confectionery whether they be poisonous or not.

(*b*) Only harmless colors or flavors shall be added to confectionery.

(*c*) The term "narcotic drugs" includes all the drugs mentioned in section 8, food and drugs act, June 30, 1906, relating to foods, their derivatives and preparations, and all other drugs of a narcotic nature.

Regulation 11. Substances Mixed and Packed with Foods.

(Section 7, under "Foods.")

No substance may be mixed or packed with a food product which will reduce or lower its quality or strength. Not excluded under this provision are substances properly used in the preparation of food products for clarification or refining, and eliminated in the further process of manufacture.

Regulation 12. Coloring, Powdering, Coating, and Staining.

(Section 7, under "Foods.")

(*a*) Only harmless colors may be used in food products.

(*b*) The reduction of a substance to a powder to conceal inferiority in character is prohibited.

(*c*) The term "powdered" means the application of any powdered substance to the exterior portion of articles of food, or the reduction of a substance to a powder.

(*d*) The term "coated" means the application of any substance to the exterior portion of a food product.

(*e*) The term "stain" includes any change produced by the addition of any substance to the exterior portion of foods which in any way alters their natural tint.

Regulation 13. Natural Poisonous or Deleterious Ingredients.

(Section 7, paragraph 5, under "Foods.")

Any food product which contains naturally a poisonous or deleterious ingredient does not come within the provisions of the food and drugs act, June 30, 1906, except when the presence of such ingredient is due to filth, putrescence, or decomposition.

Regulation 14. External Application of Preservatives.

(Section 7, paragraph 5, under "Foods," proviso.)

(*a*) Poisonous or deleterious preservatives shall only be applied externally, and they and the food products shall be of a character which shall not permit the permeation of any of the preservative to the interior, or any portion of the interior, of the product.

(*b*) When these products are ready for consumption, if any portion of the added preservative shall have penetrated the food product, then the proviso of section 7, paragraph 5, under "Foods," shall not obtain, and such food products shall then be subject to the regulations for food products in general.

(*c*) The preservative applied must be of such a character that, until removed, the food products are inedible.

Regulation 15. Wholesomeness of Colors and Preservatives.

[As amended to accord with F. I. D. 104. See also F. I. D. 7, 29, 96, 101, 102, 135, and 178 for rulings under this head.]

(Section 7, paragraph 5, under "Foods.")

(*a*) Respecting the wholesomeness of colors, preservatives, and other substances which are added to foods, the Secretary of Agriculture shall determine from chemical or other examination, under the authority of the agricultural appropriation act, Public 382, approved June 30, 1906, the names of those substances which are permitted or inhibited in food products; and such findings, when approved by the Secretary of the Treasury and the Secretary of Commerce and Labor, shall become a part of these regulations.

(*b*) The Secretary of Agriculture shall determine from time to time, in accordance with the authority conferred by the agricultural appropriation act, Public 382, approved June 30, 1906, the principles which shall guide the use of colors, preservatives, and other substances added to foods; and when concurred in by the Secretary of the Treasury and the Secretary of Commerce and Labor, the principles so established shall become a part of these regulations.

(*c*) It having been determined that benzoate of soda mixed with food is not deleterious or poisonous and is not injurious to health, no objection will be raised under the food and drugs act to the use in food of benzoate of soda, provided that each container or package of such food is plainly labeled to show the presence and amount of benzoate of soda. Food Inspection Decisions 76 and 89 are amended accordingly.

(*d*) It having been determined that saccharin mixed with food is an added poisonous and deleterious ingredient such as is contemplated by the act, and also that the substitution of saccharin for sugar in foods reduces and lowers their quality, the Secretary of Agriculture will regard as adulterated under the food and drugs act foods containing saccharin which, on or after April 1, 1912, are manufactured or offered for sale in the District of Columbia or Territories or shipped in interstate or foreign commerce, or offered for importation into the United States. (F. I. D. 135, 138, and 142, dated April 26 and June 20, 1911, and March 1, 1912, respectively.)

Regulation 16. Character of the Raw Materials.

(Section 7, paragraph 1, under "Drugs;" paragraph 6, under "Foods.")

(*a*) The Secretary of Agriculture, when he deems it necessary, shall examine the raw materials used in the manufacture of food and drug products, and determine whether any filthy, decomposed, or putrid substance is used in their preparation.

(*b*) The Secretary of Agriculture shall make such inspections as often as he may deem necessary.

MISBRANDING.

Regulation 17. Label.

[As amended by F. I. D. 81, January 21, 1908, taking effect February 10, 1908.]

(Section 8.)

(*a*) The term "label" applies to any printed, pictorial or other matter upon or attached to any package of a food or drug product, or any container thereof subject to the provisions of this act.

(*b*) The principal label shall consist, first, of all information which the food and drugs act, June 30, 1906, specifically requires, to wit, the name of the place of manufacture in the case of food compounds or mixtures sold under a distinctive name; statements which show that the articles are compounds, mixtures, or blends; the words "compound," "mixture," or "blend," and words designating substances or their derivatives and proportions required to be named in the case of foods and drugs. All this information shall appear upon the principal label, and should have no intervening descriptive or explanatory reading matter. Second, if the name of the manufacturer and place of

manufacture are given, they should also appear upon the principal label. Third, preferably upon the principal label, in conjunction with the name of the substance, such phrases as "artificially colored," "colored with sulphate of copper," or any other such descriptive phrases necessary to be announced should be conspicuously displayed. Fourth, elsewhere upon the principal label other matter may appear in the discretion of the manufacturer. If the contents are stated in terms of weight or measure, such statement should appear upon the principal label and must be couched in plain terms, as required by Regulation 29.

(*c*) If the principal label is in a foreign language, all information required by law and such other information as indicated above in (*b*) shall appear upon it in English. Besides the principal label in the language of the country of production, there may be also one or more other labels, if desired, in other languages, but none of them more prominent than the principal label, and these other labels must bear the information required by law, but not necessarily in English. The size of the type used to declare the information required by the act shall not be smaller than 8-point (brevier) capitals: *Provided*, That in case the size of the package will not permit the use of 8-point type, the size of the type may be reduced proportionately.

(*d*) Descriptive matter upon the label shall be free from any statement, design, or device regarding the article or the ingredients or substances contained therein, or quality thereof, or place of origin, which is false or misleading in any particular. The term "design" or "device" applies to pictorial matter of every description, and to abbreviations, characters, or signs for weights, measures, or names of substances.

(*e*) An article containing more than one food product or active medicinal agent is misbranded if named after a single constituent.

In the case of drugs the nomenclature employed by the United States Pharmacopœia and the National Formulary shall obtain.

(*f*) The use of any false or misleading statement, design, or device appearing on any part of the label shall not be justified by any statement given as the opinion of an expert or other person, nor by any descriptive matter explaining the use of the false or misleading statement given as the opinion of an expert or other person, nor by any descriptive matter explaining the use of the false or misleading statement, design, or device.

Regulation 18. Name and Address of Manufacturer.

(Section 8.)

(*a*) The name of the manufacturer or producer, or the place where manufactured, except in case of mixtures and compounds having a distinctive name, need not be given upon the label, but if given, must be the true name and the true place. The words "packed for ———,"

"distributed by ———," or some equivalent phrase, shall be added to the label in case the name which appears upon the label is not that of the actual manufacturer or producer, or the name of the place not the actual place of manufacture or production.

(*b*) When a person, firm, or corporation actually manufactures or produces an article of food or drug in two or more places, the actual place of manufacture or production of each particular package need not be stated on the label except when in the opinion of the Secretary of Agriculture the mention of any such place, to the exclusion of the others, misleads the public.

Regulation 19. Character of Name.

[As amended by F. I. D. 84, January 31, 1908, taking effect February 10, 1908.]

(Section 8.)

(*a*) A simple or unmixed food or drug product not bearing a distinctive name should be designated by its common name in the English language; or if a drug, by any name recognized in the United States Pharmacopœia or National Formulary. No further description of the components or qualities is required, except as to content of alcohol, morphine, etc.

(*b*) The use of a geographical name shall not be permitted in connection with a food or drug product not manufactured or produced in that place, when such name indicates that the article was manufactured or produced in that place.

(*c*) The use of a geographical name in connection with a food or drug product will not be deemed a misbranding when by reason of long usage it has come to represent a generic term and is used to indicate a style, type, or brand; but in all such cases the State or Territory where any such article is manufactured or produced shall be stated upon the principal label.

(*d*) A foreign name which is recognized as distinctive of a product of a foreign country shall not be used upon an article of domestic origin except as an indication of the type or style of quality or manufacture, and then only when so qualified that it can not be offered for sale under the name of a foreign article.

Regulation 20. Distinctive Name.

(Section 8.)

(*a*) A "distinctive name" is a trade, arbitrary, or fancy name which clearly distinguishes a food product, mixture, or compound from any other food product, mixture, or compound.

(*b*) A distinctive name shall not be one representing any single constituent of a mixture or compound.

(*c*) A distinctive name shall not misrepresent any property or quality of a mixture or compound.

(*d*) A distinctive name shall give no false indication of origin, character, or place of manufacture, nor lead the purchaser to suppose that it is any other food or drug product.

Regulation 21. Compounds, Imitations, or Blends Without Distinctive Name.

(Section 8.)

(*a*) The term "blend" applies to a mixture of like substances, not excluding harmless coloring or flavoring ingredients used for the purpose of coloring and flavoring only.

(*b*) If any age is stated, it shall not be that of a single one of its constituents, but shall be the average of all constituents in their respective proportions.

(*c*) Coloring and flavoring can not be used for increasing the weight or bulk of a blend.

(*d*) In order that colors or flavors may not increase the volume or weight of a blend, they are not to be used in quantities exceeding 1 pound to 800 pounds of the blend.

(*e*) A color or flavor can not be employed to imitate any natural product or any other product of recognized name and quality.

(*f*) The term "imitation" applies to any mixture or compound which is a counterfeit or fraudulent simulation of any article of food or drug.

Regulation 22. Articles without a Label.

(Section 8, paragraph 1, under "Drugs;" paragraph 1, under "Foods.")

It is prohibited to sell or offer for sale a food or drug product bearing no label upon the package or no descriptive matter whatever connected with it, either by design, device, or otherwise, if said product be an imitation of or offered for sale under the name of another article.

Regulation 23. Proper Branding not a Complete Guaranty.

Packages which are correctly branded as to character of contents, place of manufacture, name of manufacturer, or otherwise, may be adulterated and hence not entitled to enter into interstate commerce.

Regulation 24. Incompleteness of Branding.

A compound shall be deemed misbranded if the label be incomplete as to the names of the required ingredients. A simple product does not require any further statement than the name or distinctive name thereof, except as provided in Regulations 19 (*a*) and 28.

Regulation 25. Substitution.

(Sections 7 and 8.)

(*a*) When a substance of a recognized quality commonly used in the preparation of a food or drug product is replaced by another substance not injurious or deleterious to health, the name of the substituted substance shall appear upon the label.

(*b*) When any substance which does not reduce, lower, or injuriously affect its quality or strength, is added to a food or drug product, other than that necessary to its manufacture or refining, the label shall bear a statement to that effect.

Regulation 26. Waste Materials.

(Section 8.)

When an article is made up of refuse materials, fragments, or trimmings, the use of the name of the substance from which they are derived, unless accompanied by a statement to that effect, shall be deemed a misbranding. Packages of such materials may be labeled "pieces," "stems," "trimmings," or with some similar appellation.

Regulation 27. Mixtures or Compounds with Distinctive Names.

(Section 8. First proviso under "Foods," paragraph 1.)

(*a*) The terms "mixtures" and "compounds" are interchangeable and indicate the results of putting together two or more food products.

(*b*) These mixtures or compounds shall not be imitations of other articles, whether simple, mixt, or compound, or offered for sale under the name of other articles. They shall bear a distinctive name and the name of the place where the mixture or compound has been manufactured or produced.

(*c*) If the name of the place be one which is found in different States, Territories, or countries, the name of the State, Territory, or country, as well as the name of the place, must be stated.

Regulation 28. Substances named in Drugs or Foods.

[As amended by F. I. D. 112, January 6, 1910, taking effect April 1, 1910.]

(Section 8. Second under "Drugs;" second under "Foods.")

(*a*) The term "alcohol" is defined to mean common or ethyl alcohol. No other kind of alcohol is permissible in the manufacture of drugs except as specified in the United States Pharmacopœia or National Formulary.

(*b*) The words alcohol, morphine, opium, etc., and the quantities and proportions thereof, shall be printed in letters corresponding in size with those prescribed in Regulation 17, paragraph (*c*).

(*c*) A drug, or food product except in respect of alcohol, is misbranded in case it fails to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, heroin, cocaine, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any such substances contained therein.

(*d*) A statement of the maximum quantity or proportion of any such substances present will meet the requirements, provided the maximum stated does not vary materially from the average quantity or proportion.

(*e*) In case the actual quantity or proportion is stated it shall be the average quantity or proportion with the variations noted in Regulation 29.

(*f*) The following are the principal derivatives and preparations made from the articles which are required to be named upon the label:

ALCOHOL, ETHYL: (*Cologne spirits, Grain alcohol, Rectified spirits, Spirits, and Spirits of wine.*)

Derivatives—

Aldehyde, Ether, Ethyl acetate, Ethyl nitrite, and Paraldehyde.

Preparations containing alcohol—

Bitters, Brandies, Cordials, Elixirs, Essences, Fluidextracts, Spirits, Sirups, Tinctures, Tonics, Whiskies, and Wines.

MORPHINE, ALKALOID:

Derivatives—

Apomorphine, Dionine, Peronine, Morphine acetate, Hydrochloride, Sulphate, and other salts of morphine.

Preparations containing morphine or derivatives of morphine—

Bougies, Catarrh Snuff, Chlorodyne, Compound powder of morphine, Crayons, Elixirs, Granules, Pills, Solutions, Sirups, Suppositories, Tablets, Triturates, and Troches.

OPIUM, GUM:

Preparations of opium—

Extracts, Denarcotized opium, Granulated opium, and Powdered opium, Bougies, Brown mixture, Carminative mixtures, Crayons, Dover's powder, Elixirs, Liniments, Ointments, Paregoric, Pills, Plasters, Sirups, Suppositories, Tablets, Tinctures, Troches, Vinegars, and Wines.

Derivatives—

Codeine, Alkaloid, Hydrochloride, Phosphate, Sulphate, and other salts of codeine.

Preparations containing codeine or its salts—

Elixirs, Pills, Sirups, and Tablets.

COCAINE, ALKALOID:

Derivatives—

Cocaine hydrochloride, Oleate, and other salts.

Preparations containing cocaine or salts of cocaine—

Coca leaves, Catarrh powders, Elixirs, Extracts, Infusion of coca, Ointments, Paste pencils, Pills, Solutions, Sirups, Tablets, Tinctures, Troches, and Wines.

HEROIN:

Preparations containing heroin—

Sirups, Elixirs, Pills, and Tablets.

ALPHA AND BETA EUCAINE:

Preparations—

Mixtures, Ointments, Powders, and Solutions.

CHLOROFORM:

Preparations containing chloroform—

Chloranodyne, Elixirs, Emulsions, Liniments, Mixtures, Spirits, and Sirups.

CANNABIS INDICA:

Preparations of cannabis indica—

Corn remedies, Extracts, Mixtures, Pills, Powders, Tablets, and Tinctures.

CHLORAL HYDRATE (*Chloral*, U. S. Pharmacopœia, 1890):

Derivatives—

Chloral acetophenonoxim, Chloral alcoholate, Chloralamide, Chloralimide, Chloral orthoform, Chloralose, Dormiol, Hypnal, and Uraline.

Preparations containing chloral hydrate or its derivatives—

Chloral camphorate, Elixirs, Liniments, Mixtures, Ointments, Suppositories, Sirups, and Tablets.

ACETANILIDE (*Antifebrine, Phenylacetamide*):

Derivatives—

Acetphenetidine, Citrophen, Diacetanilide, Lactophenin, Methoxy-acetanilide, Methylacetanilide, Para-Iodoacetanilide, and Phenacetine.

Preparations containing acetanilide or derivatives—

Analgesics, Antineuralgics, Antirheumatics, Cachets, Capsules, Cold remedies, Elixirs, Granular effervescing salts, Headache powders, Mixtures, Pain remedies, Pills, and Tablets.

(*g*) In declaring the quantity or proportion of any of the specified substances the names by which they are designated in the act shall be used, and in declaring the quantity or proportion of derivatives of any of the specified substances, in addition to the trade name of the derivative, the name of the specified substance shall also be stated, so as to indicate clearly that the product is a derivative of the particular specified substance.

Regulation 29. Statement of Weight or Measure.

(Section 8. Third under "Foods.")

[The section of the law under which this regulation was made has been amended by the act of March 3, 1913, Public—No. 419, H. R. 22526. New regulations will be published as soon as they have been adopted.]

(*a*) A statement of the weight or measure of the food contained in a package is not required. If any such statement is printed, it shall be a plain and correct statement of the average net weight or volume, either on or immediately above or below the principal label, and of the size of letters specified in Regulation 17.

(*b*) A reasonable variation from the stated weight for individual packages is permissible, provided this variation is as often above as below the weight or volume stated. This variation shall be determined by the inspector from the changes in the humidity of the atmosphere, from the exposure of the package to evaporation or to absorption of water, and the reasonable variations which attend the filling and weighing or measuring of a package.

Regulation 30. Method of Stating Quantity or Proportion.

(Section 8.)

In the case of alcohol the expression "quantity" or "proportion" shall mean the average percentage by volume in the finished product. In the case of the other ingredients required to be named upon the label, the expression "quantity" or "proportion" shall mean grains or minims per ounce or fluid ounce, and also, if desired, the metric equivalents therefor, or milligrams per gram or per cubic centimeter, or grams or cubic centimeters per kilogram or per liter; provided that these articles shall not be deemed misbranded if the maximum of quantity or proportion be stated, as required in Regulation 28 (*d*).

EXPORTS AND IMPORTS OF FOODS AND DRUGS.

Regulation 31. Preparation of Food Products for Export.

(Section 2.)

(*a*) Food products intended for export may contain added substances not permitted in foods intended for interstate commerce, when the addition of such substances does not conflict with the laws of the countries to which the food products are to be exported and when such substances are added in accordance with the directions of the foreign purchaser or his agent.

(*b*) The exporter is not required to furnish evidence that goods have been prepared or packed in compliance with the laws of the foreign country to which said goods are intended to be shipped, but such shipment is made at his own risk.

(*c*) Food products for export under this regulation shall be kept separate and labeled to indicate that they are for export.

(*d*) If the products are not exported they shall not be allowed to enter interstate commerce.

Regulation 32. Imported Food and Drug Products.

(Section 11.)

(*a*) Meat and meat food products imported into the United States shall be accompanied by a certificate of official inspection of a character to satisfy the Secretary of Agriculture that they are not dangerous to health, and each package of such articles shall bear a label which shall identify it as covered by the certificate, which certificate shall accompany or be attached to the invoice on which entry is made.

(*b*) The certificate shall set forth the official position of the inspector and the character of the inspection.

(*c*) Meat and meat food products as well as all other food and drug products of a kind forbidden entry into or forbidden to be sold, or

restricted in sale in the country in which made or from which exported, will be refused admission.

(*d*) Meat and meat food products which have been inspected and passed through the customs may, if identity is retained, be transported in interstate commerce.

Regulation 33. Declaration.

(Section 11.)

(*a*) All invoices of food or drug products shipped to the United States shall have attached to them a declaration of the shipper, made before a United States consular officer, as follows:

I, the undersigned, do solemnly and truly declare that I am the ——— ——— of (Manufacturer, agent, or shipper.)
the merchandise herein mentioned and described, and that it consists of food or drug products which contain no added substances injurious to health.

These products were grown in ——— and manufactured in ——— by ——— (Country.) (Country.) (Name of manufacturer.)
——— during the year ———, and are exported from ——— and consigned to ———, (City.) (City.)

The products bear no false labels or marks, contain $\frac{\text{no}}{\text{some}}$ added coloring matter or preservative ———, and are not of a character to cause prohibition or restriction (Name of added color or preservative.)
in the country where made or from which exported.

Dated at —— this —— day of ——, 19 —.

(Signed): ——— ——— ———.

(*b*) In the case of importations to be entered at New York, Boston, Philadelphia, Chicago, San Francisco, and New Orleans, and other ports where food and drug inspection laboratories shall be established, this declaration shall be attached to the invoice on which entry is made. In other cases the declaration shall be attached to the copy of the invoice sent to the Bureau of Chemistry.

Regulation 34. Denaturing.

[As amended by F. I. D. 93, May 12, 1908.]

(Section 11.)

Unless otherwise declared on the invoice, all substances ordinarily used as food products will be treated as such. Shipments of substances ordinarily used as food products intended for technical purposes should be accompanied by a declaration stating that fact. Such products should be denatured before entry, but denaturing may be allowed under customs supervision with the consent of the Secretary of the Treasury, or the Secretary of the Treasury may release such products without denaturing, under such conditions as may preclude the possibility of their use as food products.

Regulation 35. Bond, Imported Foods, and Drugs.

(Section 11.)

Unexamined packages of food and drug products may be delivered to the consignee prior to the completion of the examination to determine whether the same are adulterated or misbranded upon the execution of a penal bond by the consignee in the sum of the invoice value of such goods with the duty added, for the return of the goods to customs custody.

Regulation 36. Notification of Violation of the Law.

(Section 11.)

If the sample on analysis or examination be found not to comply with the law, the importer shall be notified of the nature of the violation, the time and place at which final action will be taken upon the question of the exclusion of the shipment, and that he may be present, and submit evidence (Form No. 5), which evidence, with a sample of the article, shall be forwarded to the Bureau of Chemistry at Washington, accompanied by the appropriate report card.

Regulation 37. Appeal to the Secretary of Agriculture and Remuneration.

(Section 11.)

All applications for relief from decisions arising under the execution of the law should be addrest to the Secretary of Agriculture, and all vouchers or accounts for remuneration for samples shall be filed with the chief of the inspection laboratory, who shall forward the same, with his recommendation, to the Department of Agriculture for action.

Regulation 38. Shipment beyond the jurisdiction of the United States.

(Section 11.)

The time allowed the importer for representations regarding the shipment may be extended at his request to permit him to secure such evidence as he desires, provided that this extension of time does not entail any expense to the Department of Agriculture. If at the expiration of this time, in view of the data secured in inspecting the sample and such evidence as may have been submitted by the manufacturers or importers, it apppears that the shipment can not be legally imported into the United States, the Secretary of Agriculture shall request the Secretary of the Treasury to refuse to deliver the shipment in question to the consignee, and to require its reshipment beyond the jurisdiction of the United States

Regulation 39. Application of Regulations.

These regulations shall not apply to domestic meat and meat food products which are prepared, transported, or sold in interstate or foreign commerce under the meat-inspection law and the regulations of the Secretary of Agriculture made thereunder.

Regulation 40. Alteration and Amendment of Regulations.

These regulations may be altered or amended at any time, without previous notice, with the concurrence of the Secretary of the Treasury, the Secretary of Agriculture, and the Secretary of Commerce and Labor.

THE FOOD AND DRUGS ACT, JUNE 30, 1906, AS AMENDED AUGUST 23, 1912.

AN ACT For preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That it shall be unlawful for any person to manufacture within any Territory or the District of Columbia any article of food or drug which is adulterated or misbranded, within the meaning of this Act; and any person who shall violate any of the provisions of this section shall be guilty of a misdemeanor, and for each offense shall, upon conviction thereof, be fined not to exceed five hundred dollars or shall be sentenced to one year's imprisonment, or both such fine and imprisonment, in the discretion of the court, and for each subsequent offense and conviction thereof shall be fined not less than one thousand dollars or sentenced to one year's imprisonment, or both such fine and imprisonment, in the discretion of the court.

SEC. 2. That the introduction into any State or Territory or the District of Columbia from any other State or Territory or the District of Columbia, or from any foreign country, or shipment to any foreign country of any article of food or drugs which is adulterated or misbranded, within the meaning of this Act, is hereby prohibited; and any person who shall ship or deliver for shipment from any State or Territory or the District of Columbia to any other State or Territory or the District of Columbia, or to a foreign country, or who shall receive in any State or Territory or the District of Columbia from any other State or Territory or the District of Columbia, or foreign country, and having so received, shall deliver, in original unbroken packages, for pay or otherwise, or offer to deliver to any other person, any such article so adulterated or misbranded within the meaning of this Act, or any person who shall sell or offer for sale in the District of Columbia or the Territories of the United States any such adulterated or misbranded foods or drugs, or export or offer to export the same to any foreign country, shall be guilty of a misdemeanor, and for such offense be fined not exceeding two hundred dollars for the first offense, and upon conviction for each subsequent offense not exceeding three hundred dollars or be imprisoned not exceeding one year, or both, in the discretion of the court: *Provided*, That no article shall be deemed misbranded or adulterated within the provisions of this Act when intended for export to any foreign country and prepared or packed according to the specifications or directions of the foreign purchaser when no substance is used in the preparation or packing thereof in conflict with the laws of the foreign country to which said article is intended to be shipped; but if said article shall be in fact sold or offered for sale for domestic use or consumption, then this proviso shall not exempt said article from the operation of any of the other provisions of this Act.

SEC. 3. That the Secretary of the Treasury, the Secretary of Agriculture, and the Secretary of Commerce and Labor shall make uniform rules and regulations for carrying out the provisions of this Act, including the collection and examination of specimens of foods and drugs manufactured or offered for sale in the District of Columbia, or in any Territory of the United States, or which shall be offered for sale in unbroken packages in any State other than that in which they shall have been respectively manufactured or produced, or which shall be received from any foreign country, or intended for shipment to any foreign country, or which may be submitted for examination by the chief health, food, or drug officer of any State, Territory,

or the District of Columbia, or at any domestic or foreign port through which such product is offered for interstate commerce, or for export or import between the United States and any foreign port or country.

SEC. 4. That the examinations of specimens of foods and drugs shall be made in the Bureau of Chemistry of the Department of Agriculture, or under the direction and supervision of such Bureau, for the purpose of determining from such examinations whether such articles are adulterated or misbranded within the meaning of this Act; and if it shall appear from any such examination that any of such specimens is adulterated or misbranded within the meaning of this Act, the Secretary of Agriculture shall cause notice thereof to be given to the party from whom such sample was obtained. Any party so notified shall be given an opportunity to be heard, under such rules and regulations as may be prescribed as aforesaid, and if it appears that any of the provisions of this Act have been violated by such party, then the Secretary of Agriculture shall at once certify the facts to the proper United States district attorney, with a copy of the results of the analysis or the examination of such article duly authenticated by the analyst or officer making such examination, under the oath of such officer. After judgment of the court, notice shall be given by publication in such manner as may be prescribed by the rules and regulations aforesaid.

SEC. 5. That it shall be the duty of each district attorney to whom the Secretary of Agriculture shall report any violation of this Act, or to whom any health or food or drug officer or agent of any State, Territory, or the District of Columbia shall present satisfactory evidence of any such violation, to cause appropriate proceedings to be commenced and prosecuted in the proper courts of the United States, without delay, for the enforcement of the penalties as in such case herein provided.

SEC. 6. That the term "drug" as used in this Act, shall include all medicines and preparations recognized in the United States Pharmacopœia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals. The term "food," as used herein, shall include all articles used for food, drink, confectionery, or condiment by man or other animals, whether simple, mixed, or compound.

SEC. 7. That for the purposes of this Act an article shall be deemed to be adulterated:

In case of drugs:

First. If, when a drug is sold under or by a name recognized in the United States Pharmacopœia or National Formulary, it differs from the standard of strength, quality, or purity, as determined by the test laid down in the United States Pharmacopœia or National Formulary official at the time of investigation: *Provided*, That no drug defined in the United States Pharmacopœia or National Formulary shall be deemed to be adulterated under this provision if the standard of strength, quality, or purity be plainly stated upon the bottle, box, or other container thereof although the standard may differ from that determined by the test laid down in the United States Pharmacopœia or National Formulary.

Second. If its strength or purity fall below the professed standard or quality under which it is sold.

In the case of confectionery:

If it contain terra alba, barytes, talc, chrome yellow, or other mineral substance or poisonous color or flavor, or other ingredient deleterious or detrimental to health, or any vinous, malt, or spirituous liquor or compound or narcotic drug.

In the case of food:

First. If any substance has been mixed and packed with it so as to reduce or lower or injuriously affect its quality or strength.

Second. If any substance has been substituted wholly or in part for the article.

Third. If any valuable constituent of the article has been wholly or in part abstracted.

Fourth. If it be mixed, colored, powdered, coated, or stained in a manner whereby damage or inferiority is concealed.

Fifth. If it contain any added poisonous or other added deleterious ingredient which may render such article injurious to health: *Provided*, That when in the preparation of food products for shipment they are preserved by any external application applied in such manner that the preservative is necessarily removed mechanically, or by maceration in water, or otherwise, and directions for the removal of said preservative shall be printed on the covering or the package, the provisions of this Act shall be construed as applying only when said products are ready for consumption.

Sixth. If it consists in whole or in part of a filthy, decomposed, or putrid animal or vegetable substance, or any portion of an animal unfit for food, whether manufactured or not, or if it is the product of a diseased animal, or one that has died otherwise than by slaughter.

SEC. 8. That the term "misbranded," as used herein, shall apply to all drugs, or articles of food, or articles which enter into the composition of food, the package or label of which shall bear any statement, design, or device regarding such article, or the ingredients or substances contained therein which shall be false or misleading in any particular, and to any food or drug product which is falsely branded as to the State, Territory, or country in which it is manufactured or produced.

That for the purposes of this Act an article shall also be deemed to be misbranded:

In case of drugs:

First. If it be an imitation of or offered for sale under the name of another article.

Second. If the contents of the package as originally put up shall have been removed, in whole or in part, and other contents shall have been placed in such package, or if the package fail to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any such substances contained therein.

Third. If its package or label shall bear or contain any statement, design, or device regarding the curative or therapeutic effect of such article or any of the ingredients or substances contained therein, which is false and fraudulent.

In the case of food:

First. If it be an imitation of or offered for sale under the distinctive name of another article.

Second. If it be labeled or branded so as to deceive or mislead the purchaser, or purport to be a foreign product when not so, or if the contents of the package as originally put up shall have been removed in whole or in part and other contents shall have been placed in such package, or if it fail to bear a statement on the label of the quantity or proportion of any morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any of such substances contained therein.

Third.[1] If in package form, the quantity of the contents be not plainly and conspicuously marked on the outside of the package in terms of weight, measure, or numerical count: *Provided, however*, That reasonable variations shall be permitted, and tolerances and also exemptions as to small packages shall be established by rules and regulations made in accordance with the provisions of section three of this Act.

Fourth. If the package containing it or its label shall bear any statement, design, or device regarding the ingredients or the substances contained therein, which statement, design, or device shall be false or misleading in any particular: *Provided*, That

[1] The act of March 3, 1913, provides that no penalty of fine, imprisonment, or confiscation shall be enforced for any violation of its provisions as to domestic products prepared or foreign products imported prior to eight on months after its passage.

an article of food which does not contain any added poisonous or deleterious ingredients shall not be deemed to be adulterated or misbranded in the following cases:

First. In the case of mixtures or compounds which may be now or from time to time hereafter known as articles of food, under their own distinctive names, and not an imitation of or offered for sale under the distinctive name of another article, if the name be accompanied on the same label or brand with a statement of the place where said article has been manufactured or produced.

Second. In the case of articles labeled, branded, or tagged so as to plainly indicate that they are compounds, imitations, or blends, and the word "compound," "imitation," or "blend," as the case may be, is plainly stated on the package in which it is offered for sale: *Provided*, That the term blend as used herein shall be construed to mean a mixture of like substances, not excluding harmless coloring or flavoring ingredients used for the purpose of coloring and flavoring only: *And provided further*, That nothing in this Act shall be construed as requiring or compelling proprietors or manufacturers of proprietary foods which contain no unwholesome added ingredient to disclose their trade formulas, except in so far as the provisions of this act may require to secure freedom from adulteration or misbranding.

SEC. 9. That no dealer shall be prosecuted under the provisions of this Act when he can establish a guaranty signed by the wholesaler, jobber, manufacturer, or other party residing in the United States, from whom he purchases such articles, to the effect that the same is not adulterated or misbranded within the meaning of this Act, designating it. Said guaranty, to afford protection, shall contain the name and address of the party or parties making the sale of such articles to such dealer, and in such case said party or parties shall be amenable to the prosecutions, fines and other penalties which would attach, in due course, to the dealer under the provisions of this Act.

SEC. 10. That any article of food, drug, or liquor that is adulterated or misbranded within the meaning of this Act, and is being transported from one State, Territory, District, or insular possession to another for sale, or, having been transported, remains unloaded, unsold, or in original unbroken packages, or if it be sold or offered for sale in the District of Columbia or the Territories, or insular possessions of the United States, or if it be imported from a foreign country for sale, or if it is intended for export to a foreign country, shall be liable to be proceeded against in any district court of the United States within the district where the same is found, and seized for confiscation by a process of libel for condemnation. And if such article is condemned as being adulterated or misbranded, or of a poisonous or deleterious character, within the meaning of this Act, the same shall be disposed of by destruction or sale, as the said court may direct, and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States, but such goods shall not be sold in any jurisdiction contrary to the provisions of this Act or the laws of that jurisdiction: *Provided, however*, That upon the payment of the costs of such libel proceedings and the execution and delivery of a good and sufficient bond to the effect that such articles shall not be sold or otherwise disposed of contrary to the provisions of this Act, or the laws of any State, Territory, District, or insular possession, the court may by order direct that such articles be delivered to the owner thereof. The proceedings of such libel cases shall conform, as near as may be, to the proceedings in admiralty, except that either party may demand trial by jury of any issue of fact joined in any such case, and all such proceedings shall be at the suit of and in the name of the United States.

SEC. 11. The Secretary of the Treasury shall deliver to the Secretary of Agriculture, upon his request from time to time, samples of foods and drugs which are being imported into the United States or offered for import, giving notice thereof to the owner or consignee, who may appear before the Secretary of Agriculture, and have the right to introduce testimony, and if it appear from the examination of such sam-

ples that any article of food or drug offered to be imported into the United States is adulterated or misbranded within the meaning of this Act, or is otherwise dangerous to the health of the people of the United States, or is of a kind forbidden entry into, or forbidden to be sold or restricted in sale in the country in which it is made or from which it is exported, or is otherwise falsely labeled in any respect, the said article shall be refused admission, and the Secretary of the Treasury shall refuse delivery to the consignee and shall cause the destruction of any goods refused delivery which shall not be exported by the consignee within three months from the date of notice of such refusal under such regulations as the Secretary of the Treasury may prescribe: *Provided*, That the Secretary of the Treasury may deliver to the consignee such goods pending examination and decision in the matter on execution of a penal bond for the amount of the full invoice value of such goods, together with the duty thereon, and on refusal to return such goods for any cause to the custody of the Secretary of the Treasury, when demanded, for the purpose of excluding them from the country, or for any other purpose, said consignee shall forfeit the full amount of the bond: *And provided further*, That all charges for storage, cartage, and labor on goods which are refused admission or delivery shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against any future importation made by such owner or consignee.

SEC. 12. That the term "Territory" as used in this Act shall include the insular possessions of the United States. The word "person" as used in this Act shall be construed to import both the plural and the singular, as the case demands, and shall include corporations, companies, societies and associations. When construing and enforcing the provisions of this Act, the act, omission, or failure of any officer, agent, or other person acting for or employed by any corporation, company, society, or association, within the scope of his employment or office, shall in every case be also deemed to be the act, omission, or failure of such corporation, company, society, or association as well as that of the person.

SEC. 13. That this Act shall be in force and effect from and after the first day of January, nineteen hundred and seven.

Approved June 30, 1906.

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Supreme Court of the United States

OCTOBER TERM, 1913

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No. 118

THE UNITED STATES OF AMERICA, *Plaintiff in Error and Appellant,*

vs.

THE ANTIKAMNIA CHEMICAL COMPANY,

IN ERROR TO AND ON APPEAL FROM THE COURT OF APPEALS OF THE DISTRICT OF COLUMBIA.

MOTIONS TO DISMISS OR AFFIRM.

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FRANK J. HOGAN,
Attorneys for Defendant in Error and Appellee.

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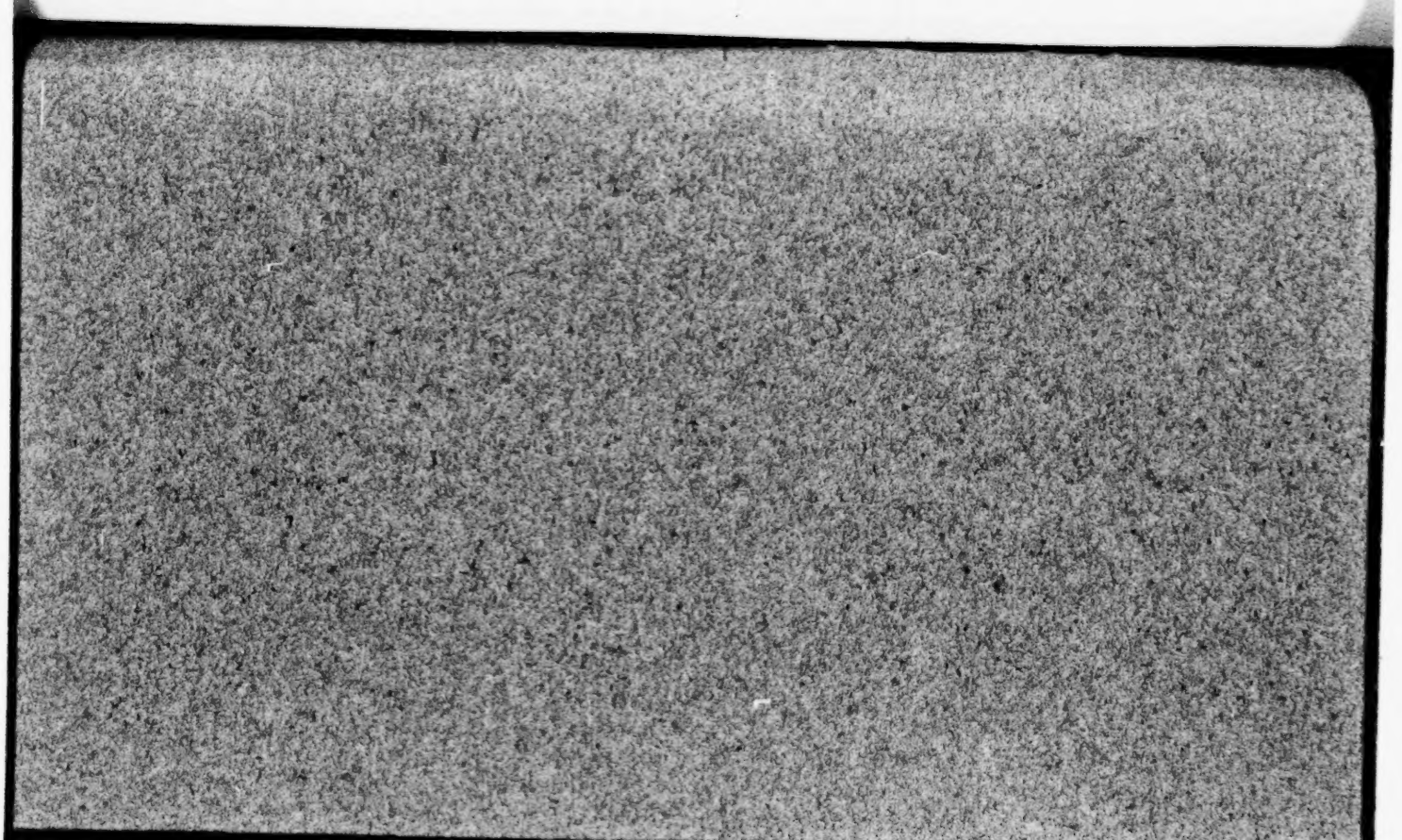

Supreme Court of the United States

OCTOBER TERM, 1911.

No. 836.

THE UNITED STATES OF AMERICA, *Plaintiff in Error and Appellant,*

vs.

THE ANTIKAMNIA CHEMICAL COMPANY.

MOTIONS TO DISMISS OR AFFIRM.

Comes here now The Antikamnia Chemical Company, the defendant in error and appellee, and moves the Court as follows:

1. To dismiss the writ of error and appeal for want of jurisdiction.

2. To affirm the judgment or decree on the ground that it is manifest that the writ of error and appeal show that the questions upon which the disposition of the cause depends are so frivolous as not to need further argument.

DANIEL W. BAKER,
JOSEPH C. SHEEHY,
FRANK J. HOGAN,
Attorneys for Defendant in Error and Appellee.

MEMORANDUM.

Statement of Case.

This case involves nothing but the construction of the act of Congress of June 30, 1906, 34 St. L. 738, popularly known as the Food and Drugs Act. The cause comes up from the Court of Appeals of the District of Columbia on both writ of error brought and appeal taken by the United States to review a judgment or decree of that court affirming a judgment or decree of the Supreme Court of the District of Columbia sustaining exceptions to and dismissing a libel filed July 7, 1910, for the seizure and condemnation of one hundred packages of a certain drug known as Antikamnia Tablets, Antikamnia and Codein Tablets, and Antikamnia and Quinine Tablets, which libel was based upon the act of Congress above mentioned.

The libel (Record, pp. 1-4) alleges that the said drug is used and intended to be used for the cure and mitigation and prevention of disease of man; that the said packages of the said drug are illegally held within the court's jurisdiction for that the same are misbranded in violation of the said act, and are liable to confiscation and condemnation as provided therein, for the reasons following (Record, p. 3):

> "Because each and all of said packages of drug contain a large quantity and proportion of acetphenetidin, which your libelant charges is a derivative of acetanilid, and that under the provisions of the said Act of Congress and of the regulations lawfully made thereunder, it is provided and required that the label on each of said packages should bear a statement that the acetphenetidin contained therein is a derivative of acetanilid; and yet your libelant charges that each and all of said packages fail to bear a statement in any form that the acetphenetidin contained therein is a de-

rivative of acetanilid, or that the said drug contains any derivative of acetanilid.

"Your libelant further charges that each and all of said packages of drug are further misbranded, in that the labels thereon are false and misleading, for the reason that each and all of said labels bear the statement that no acetanilid is contained therein, and that said statement imports and signifies that there is no quantity or proportion of any derivative of acetanilid contained in said drug."

On July 12, 1910, the warrant issued, in virtue of which the said packages were arrested by the marshal and taken into his custody (Record, pp. 4-5); thereupon The Antikamnia Chemical Company presented its petition, asserting its sole ownership of the said packages, and praying to be made a defendant in the cause, for the protection of its rights (Record, p. 5); on consideration of this petition the court passed an order (Record, p. 6) on October 3, 1910, making the petitioner a party defendant, with full rights to litigate any questions that may arise; thereupon, on October 3, 1910, the petitioner filed nine exceptions (Record, pp. 6-8) to the said libel; these exceptions were sustained, and the libel was dismissed (Record, p. 8) on November 21, 1910; from this judgment or decree the Government appealed (Record, p. 8) to the Court of Appeals, which affirmed the said judgment or decree on May 29, 1911 (Record, p. 21); on October 3, 1911, the Government filed its assignment of errors (Record, p. 22), and prayed and was allowed both an appeal and a writ of error in the cause (Record, p. 22); and thereupon the writ of error and citations were issued (Record, pp. 23-24) and accepted.

Section 8 of the Food and Drugs Act of June 30, 1906, paragraph "Second," under "Drugs," provides that a drug shall be deemed to be misbranded—

> "If the package fail to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any such substances contained therein."

This section, on the recommendation of the Board of Food and Drug Inspection, *was amended by the three Secretaries* by adding thereto the following, designated as paragraph (g) of Regulation 28:

> "In declaring the quantity or proportion of any of the specified substances the names by which they are designated in the act shall be used, and in declaring the quantity or proportion of derivatives of any of the specified substances, in addition to the trade name of the derivative, the name of the specified substance shall also be stated, so as to indicate clearly that the product is a derivative of the particular specified substance."

The Board of Secretaries also defined the meaning and the scope of this new paragraph, in these words (Record, p. 10):

> "This paragraph (g) prescribes, in effect, that in labeling derivatives the name of the specified substance must be stated, so as to clearly indicate that the product is a derivative of the particular substance named in the act."

The substance of the exceptions to the libel is thus stated by the court below (Record, p. 15):

> "The exceptions on which the libel was dismissed are substantially: That the act does not require that the label on each of said packages shall have a state-

> ment that the acetphenetidin contained therein is a derivative of acetanilide, nor is it necessary under said act that a derivative of any parent substance should state that it is a derivative of such substance, provided the derivative itself is named by its proper name. That the statement on the packages that it contains no acetanilide is neither false nor misleading, but true, and the libel while charging that acetphenetidin is a derivative of acetanilide, does not charge that there is any acetanilide in acetphenetidin."

The court below sets out (Record, pp. 15-16) the contents of the several sections of the statute, and quotes (Record, p. 16) section 8 in full; and also states the details, and in part quotes (Record, p. 17) the language of Regulation 28 as amended to take effect April 1, 1910.

(NOTE: In the court's quotation of section 8 (Record, p. 16) the exceedingly important word "such" is inadvertently omitted between the words "any" and "substances" in the last line thereof.)

The short record has been printed in its entirety by the defendant in error and appellee, in support of the instant motions.

As we have already said, the questions involved in this case arise solely upon the construction of the above mentioned act; and these questions are thus stated by the court below (Record, pp. 17, 18-19, 20, 21):

> "The substantial questions for determination arise upon two propositions that have been submitted in support of the contention of error in the dismissal of the bill on the exceptions stated. The first of these is: That the packages of the drug are misbranded, because the labels fail to recite that acetphenetidin contained therein is a derivative of acetanilide.

"It seems clear that this omission is not in express violation of the requirement of section 8 of the act, for the reason that the label states the true name of the drug—acetphenetidine, which, though not one of those specifically named in the section, is a derivative of one of them—acetanilide.

* * * * * * * * * * * * *

"It must be borne in mind that the Food and Drugs Act does not confer upon executive officers the power to prescribe the forms of brands and labels upon drugs, as was done by the Oleomargarine Act, that was considered in Kollock's case, *supra*. The only power conferred is that, in section 3, which provides that the three secretaries named 'shall make uniform rules and regulations for the carrying out of the provisions of this act, including the collection and examination of specimens of food and drugs,' etc. * * *

"Section 8 declares when an article shall be deemed to be misbranded: 'First, If it be an imitation of, or offered for sale under the name of another article.' 'Second, If (among other things) the package fail to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, choral hydrate, or any derivative or preparation of any such substances contained therein.'

"In so far as the regulation designates the several derivatives of the drugs enumerated in section 8, and the preparations containing the same, we are of the opinion that it is within the power conferred in section 3 to make uniform rules and regulations for carrying out the provisions of the act. It was not reasonably practicable for Congress to ascertain and declare these several derivatives and preparations, which might then have existed, much less to anticipate those which might later come into existence and use. Having declared that the quantity or proportion of the several derivatives of the named drugs shall be stated on the labels, the ascertainment of such derivatives was a matter of detail properly confined to the executive officers in car-

rying out the provisions of the law. The regulation having named acetphenetidine as a derivative of acetanilide, the manufacturer complied therewith to the extent of naming the proportion of said derivative contained in the antikamnia tablets, but did not comply with the requirement of the same that it should also recite that it was, in fact, a derivative of acetanilide. The last requirement was, in our opinion, an amendment of or an addition to the act itself, and therefore beyond the powers of the executive authority. Congress reserved to itself the statement of the contents of the labels and did not require that when a drug was a derivative, merely, the name of the drug from whence derived should also be recited. Had it intended that this should be done, it would have so declared distinctly.

* * * * * * * * * * * *

"The second proposition is this in substance: The statement on the label that the drug 'contains no acetanilide' is false and misleading, and constitutes misbranding within the meaning of the act. The libel does not expressly charge that acetphenetidine contains acetanilide. If it did, there would be no doubt of the soundness of the proposition, for the exceptions necessarily admit every fact plainly alleged. But it contains no such allegation. It charges that the labels are false and misleading 'for the reason that each and all of said labels bear the statement that no acetanilide is contained therein, and that said statement imports and signifies that there is no quantity or proportion of any derivative of acetanilide contained in said drug."

* * * * * * * * * * * *

"As before pointed out, the libel does not charge that the statement that the preparation contains no acetanilide is false by reason of the fact that acetphenetidine does contain acetanilide. It carefully confines itself to the allegation that the statement is false because it does not recite that there is no quantity or proportion of any derivative of acetanilide contained therein. This clearly limits the charge of misbranding to

> the failure to state that acetphenetidine is a derivative of acetanilide. This is but another form of the complaint that the regulation has been violated. It does not raise an issue of fact as to whether acetphenetidine actually contains a perceptible quantity of acetanilide."

The Government's assignment of errors (Record, p. 22) on this writ of error and appeal shows conclusively that the only matters complained of are the alleged errors of the Court of Appeals in its construction of the said statute.

The matter in dispute in this case is of but insignficant value,—in fact, it does not exceed the sum of eighty-five dollars ($85); there is not involved the validity of any patent or copyright, nor is there drawn in question the validity of a treaty or statute of, or an authority exercised under, the United States; but, as stated, there is involved nothing whatever but the construction of the Food and Drugs Act.

On Motion to Dismiss.

In this case the writ of error is brought and the appeal is taken in virtue of section 233 of the code of law for the District of Columbia, which carries forward section 8 of the organic act of February 9, 1893, 27 St. L., 436, creating the Court of Appeals of the District; and this familiar section reads as follows:

> **"ANY FINAL JUDGMENT OR DECREE OF THE COURT OF APPEALS MAY BE RE-EXAMINED AND AFFIRMED, REVERSED, OR MODIFIED BY THE SUPREME COURT OF THE UNITED STATES, UPON WRIT OF ERROR OR APPEAL, IN ALL CASES IN WHICH THE MATTER IN DISPUTE, EXCLUSIVE OF COSTS, SHALL EXCEED THE SUM OF FIVE THOUSAND DOLLARS, IN THE SAME MANNER AND**

UNDER THE SAME REGULATIONS AS EXISTED IN CASES OF WRITS OF ERROR ON JUDGMENTS OR APPEALS FROM DECREES RENDERED IN THE SUPREME COURT OF THE DISTRICT OF COLUMBIA ON FEBRUARY NINTH, EIGHTEEN HUNDRED AND NINETY-THREE, AND ALSO IN CASES, WITHOUT REGARD TO THE SUM OR VALUE OF THE MATTER IN DISPUTE, WHEREIN IS INVOLVED THE VALIDITY OF ANY PATENT OR COPYRIGHT, OR IN WHICH IS DRAWN IN QUESTION THE VALIDITY OF A TREATY OR STATUTE OF, OR AN AUTHORITY EXERCISED UNDER, THE UNITED STATES."

Section 2 of the act of March 3, 1885; section 8 of the act of February 9, 1893; and section 233 of the act of March 3, 1901, are in substance, meaning, and legal effect the same, and must therefore bear the same construction. *Sinclair v. District of Columbia*, 192 U. S., 16, 18; *Chapman v. United States*, 164 U. S., 436, 450.

On the facts shown by the record, we think that this court has no jurisdiction to review the judgment or decree of the Court of Appeals. There is no possible ground upon which such jurisdiction can rest in this case, except the single one that there is drawn in question the validity of an authority exercised under the United States.

The main question in the case is whether section 8 of the act of June 30, 1906, requires the packages to bear a statement on the labels that the acetphenetidin contained therein is a derivative of acetanilid; but this is too clearly one of mere construction to admit of any discussion.

The incidental question in the case is whether paragraph (g) of Regulation 28 is regulation or legislation; but this likewise involves nothing but the construction of the act as to the nature, scope, and extent of the authority to make

rules and regulations, conferred on the three Secretaries by the law, and in no wise draws in question the validity of that authority.

The statute itself is the authority, the validity of which must be drawn in question in order to give this court jurisdiction of the instant case.

Section 3 of the act expressly gives the three Secretaries the authority to make rules and regulations; that Congress can grant them such authority is beyond controversy; the authority actually given them is confessedly valid—no one questions it; but whether the particular regulation,—paragraph (g) of Regulation 28,—is within or without the nature, scope, or extent of that authority, involves no question whatever of its validity, but only a question of the construction of the statute giving it; in this case, an attack on the validity of the authority of the three Secretaries to make the regulation would be an attack on the validity—the constitutionality—of the statute itself,—an attack neither intended nor made; to deny the existence of any authority to make the regulation, is not to deny the validity of the authority given, but is only to question its nature, scope, or extent; validity of an authority means the power of Congress to give the authority, not the nature, scope, or extent of that given; the fact that public officers make a regulation which they think is within the scope of an authority given them by Congress, but which the courts think is not within the scope of such authority, in no wise draws in question the validity of the authority itself, but only its scope,—whether the statute does or does not give the authority to make the particular regulation; this involves only the construction of the statute, and not the validity of the authority given by it; the validity of an authority is one thing, the validity of a regulation made or an act done under it is another; the existence of an author-

ity is one thing, its validity another; a denial of the validity of an authority is one thing, a denial of a title, right, privilege, or immunity claimed under it is another; and to deny the right, claimed under the act, to make the particular regulation involved in this case, is not to deny the validity of the authority—the statute—under which such right is claimed.

Innumerable would be the cases forced upon the attention of this court if the validity of an authority exercised under the United States be drawn in question every time anyone denies the right of a federal officer to make a particular rule or regulation or to do a particular act under a particular law of Congress. It is not and cannot be that every rule or act of every federal court, every regulation or act of every federal department, or every order or act of every federal officer, made or done under the laws of Congrss, if questioned, presents an instance of the validity of an authority exercised under the United States being drawn in question. It is a confusion of legal principles to entertain the notion that because we incidentally questioned the validity of paragraph (g) of Regulation 28, on the ground that it was legislation and not regulation, we thereby necessarily questioned the validity of the authority—section 3 of the statute—which the three Secretaries supposed they exercised in promulgating this paragraph. We expressly concede the validity of the authority given them by the statute, but we merely say that paragraph (g) is outside of and beyond the nature, scope, and extent of that authority, because the authority is limited to regulation, while this paragraph extends to legislation.

If we had asserted that the statute itself was invalid because it attempted to confer upon the three Secretaries the power of legislation, and the court below had held the stat-

ute void for this reason, then we should undoubtedly have a case in which the validity of an authority exercised under the United States was drawn in question; but we did not and do not question the validity of the statute—the authority—but only the validity of the alleged regulation made—in form but not in substance—under it, for that the regulation is not within, but is without, the nature, scope, and extent of the authority given by the statute, in that the authority given is that of regulation, while that exercised is that of legislation.

Section 3 gives only the authority to make rules and regulations, not the authority to pass legislation; the question whether the particular order promulgated is regulation or legislation is wholly beside the question of the validity of the authority conferred; the authority may be entirely valid, yet the order totally invalid; regulation or legislation—regulation *vel non*—involves the construction, not the validity, of the authority exercised; and the mere fact that a federal officer says that he is—or actually is—exercising an authority under the United States, does not conclude the question whether the denial of his right to do as he does draws in question the existence or validity of such authority.

These propositions are stated with reference to the case at bar, and are to be limited to it. They are supported, we believe, by the cases in the books, to some of which we presently refer.

But let us first pause to observe that the contention that section 233 of the code of law of the District of Columbia, under which this case comes up, does not give this court jurisdiction of a case in which the existence or scope of any power or duty of an officer of the United States is drawn in question, or a case in which the construction of any law of the United States is drawn in question, is

greatly intensified, if not concluded, by comparing said section 233 with section 250 of the new judicial code, which provides:

> "Any final judgment or decree of the Court of Appeals of the District of Columbia may be re-examined and affirmed, reversed, or modified by the Supreme Court of the United States, upon writ of error or appeal, in the following cases:
> * * * * * * * * * * * *
> "Fifth. In cases in which the validity of any authority exercised under the United States, or the existence or scope of any power or duty of an officer of the United States is drawn in question.
> "Sixth. In cases in which the construction of any law of the United States is drawn in question by the defendant."

Thus it is shown to a demonstration that the new law expressly gives the very jurisdiction essential to the review of this case, and that the old law (which governs this proceeding) wholly omits—and therefore denies—such power.

We now present the following pertinent cases in which this court held that the validity of an authority exercised under the United States was not drawn in question:

South Carolina v. Seymour, 153 U. S., 353, in error to the Court of Appeals of the District of Columbia, on motion to dismiss for want of jurisdiction, the court held that on a writ of mandamus in behalf of a State to the Commissioner of Patents to register a trade-mark used by the State on intoxicating liquors in commerce with a foreign nation, and which the Commissioner of Patents has refused to register, on the ground that the State by its own laws had no authorized trade in liquors outside of its limits, the validity of an authority exercised under the United States is not drawn in question. The court says (pp. 357-358):

"The petitioner sued out this writ of error, and the defendant in error now moves to dismiss it for want of jurisdiction.

"By section 8 of the act of February 9, 1893, c. 74, established a Court of Appeals for the District of Columbia, as in the previous act of March 3, 1885, c. 355, regulating appeals from the Supreme Court of the District and the Supreme Courts of the Territories, no case can be brought to this court by appeal or writ of error, unless either 'the matter in dispute, exclusive of costs, shall exceed the sum of $5,000,' or else, without regard to the sum or value in dispute, it is a case 'wherein is involved the validity of any patent or copyright, or in which is drawn in question the validity of a treaty or statute of or an authority exercised under the United States.' 27 Stat. 434; 23 Stat. 443.

* * * * * * * * * * * *

"It is not, and could not be, pretended that in this case there was 'involved the validity of any patent or copyright;' and, in the light of previous decisions of this court, it is quite clear that there was not 'drawn in question the validity of a treaty or statute of or an authority exercised under the United States.'

"In order to come within this clause, the validity, and not the construction only, of a treaty or statute of the United States, or of an authority exercised under the United States, must be directly drawn in question."

The court then reviews and reiterates the doctrines enounced in *Snow v. United States*, 118 U. S., 346, 353; *B. & P. Ry Co. v. Hopkins*, 130 U. S., 210; *Clough v. Curtis*, 134 U. S., 361, 370; and *United States v. Lynch*, 137 U. S., 280, 285, 286, and concludes in the following words (p. 360):

"IN THE PRESENT CASE, NO OBJECTION TO THE VALIDITY OF THE ACT OF CONGRESS UNDER WHICH THE COMMISSIONER OF PATENTS ACTED WAS MADE, EITHER AT

THE HEARINGS IN THE PATENT OFFICE AND IN THE COURTS OF THE DISTRICT OF COLUMBIA, OR IN THE BRIEFS FILED BY COUNSEL IN THIS COURT. NOR WAS THE EXISTENCE OR THE LAWFULNESS OF THE AUTHORITY CONFERRED BY THAT ACT UPON THE COMMISSIONER OF PATENTS DRAWN IN QUESTION. BUT FROM THE BEGINNING TO THE END OF THE PROCEEDINGS THE ONLY CONTROVERSY WAS AS TO THE CONSTRUCTION OF THE ACT OF CONGRESS, AND CONSEQUENTLY AS TO THE NATURE AND EXTENT OF THE COMMISSIONER'S AUTHORITY. NEITHER THE QUESTION WHETHER THE COMMISSIONER RIGHTLY DECIDED UPON THE PRESUMPTIVE LAWFULNESS OF THE RIGHT OF THE STATE OF SOUTH CAROLINA TO THE TRADE-MARK SOUGHT TO BE REGISTERED, NOR THE QUESTION WHETHER THE COMMISSIONER'S DUTY WAS OF SUCH A CHARACTER THAT A WRIT OF MANDAMUS WOULD LIE TO COMPEL ITS PERFORMANCE, INVOLVED A QUESTION OF THE VALIDITY OF THE AUTHORITY EXERCISED BY HIM UNDER THE UNITED STATES.

"Writ of error dismissed for want of jurisdiction."

United States v. Lynch, 137 U. S., 280, in error to the Supreme Court of the District of Columbia, was a case where the relator in an application for mandamus sought to compel the fourth auditor and the second comptroller to audit and allow a claim for mileage on the ground that the statute provided for such mileage in terms so plain as not to admit of construction; that this court has so decided; and that hence the duty to be performed is purely ministerial; and this court dismissed the writ of error, holding that the relator did not thereby directly question the validity of the authority of the auditor to audit his account, and

of the comptroller to revise and pass upon it. This court, by Mr. Chief Justice Fuller, used the following language (pp. 283, 285, 296):

> "As the matter in dispute does not reach the jurisdictional sum or value, it is contended that this court has jurisdiction to entertain the writ of error because 'the validity of an authority exercised under the United States' was drawn in question in the case. 23 Stat., 443, c. 355.
>
> * * * * * * * * * * * *
>
> "It is now argued that the duty of the Fourth Auditor and of the Second Comptroller, under the last clause of section 2 of the act of 1835 and the decision of this court in relation to it, was merely ministerial, and that by the disallowance of relator's claim for mileage these officers exercised a discretion which they did not possess; that this was an invalid exercise of an authority under the United States; and that hence the validity of the authority was drawn in question. In order to justify this position, however, the validity of the authority must have been drawn in question directly and not incidentally. **THE VALIDITY OF A STATUTE IS NOT DRAWN IN QUESTION EVERY TIME RIGHTS CLAIMED UNDER SUCH STATUTE ARE CONTROVERTED, NOR IS THE VALIDITY OF AN AUTHORITY, EVERY TIME AN ACT DONE BY SUCH AUTHORITY IS DISPUTED. THE VALIDITY OF A STATUTE OR THE VALIDITY OF AN AUTHORITY IS DRAWN IN QUESTION WHEN THE EXISTENCE, OR CONSTITUTIONALITY, OR LEGALITY OF SUCH STATUTE OR AUTHORITY IS DENIED, AND THE DENIAL FORMS THE SUBJECT OF DIRECT INQUIRY.**
>
> "We think that the authority of the Second Comptroller and the Fourth Auditor is not thus denied here, nor the validity of that authority questioned, but that what is claimed is that *in the exercise of a valid authority, the Auditor and Comptroller erred* in respect

to an allowance, in view of the decision of this court in another case. (Our italics.)

* * * * * * * * * * * *

"The contention of the relator is, that the interpretation he puts upon the act is too obviously correct to admit of dispute, and that this court has so decided; but it does not follow, because the decision of the Comptroller and Auditor may have been erroneous, that the assertion of relator to that effect raises a cognizable controversy as to their authority to proceed at all. What the relator sought was an order coercing these officers to proceed in a particular way, and this order the Supreme Court of the District declined to grant. If we were to reverse that judgment upon the ground urged, it would not be for want of power in the Auditor to audit the account, and in the Comptroller to revise and pass upon it, but because those officers had disallowed what they ought to have allowed and erroneously construed what needed no construction. This would not in any degree involve the validity of their authority. *Snow v. United States*, 118 U. S., 346, 353; *Baltimore and Potomac Railroad Co. v. Hopkins*, 130 U. S., 210. * * *

* * * * * * * * * * * *

"The writ of error must be dismissed and it is *so ordered.*"

In *Snow v. United States*, 118 U. S., 346, the court said (pp. 352-354):

"* * * Section 2 of the act of 1885 applies not where merely an act of Congress is brought in question, but only where the validity of a statute of the United States is drawn in question, or where the validity of an authority exercised under the United States is drawn in question; but this is not limited by the requirement that the decision shall have been against such validity.

"In the present cases, the validity of a statute of the United States is not drawn in question. No such

question is presented by the bills of exceptions, or the requests for instructions, or the exceptions to the charges, or anywhere else in the record. Nor is the validity of an authority exercised under the United States drawn in question. The plaintiff in error contends that the construction of the act of 1882 is drawn in question, and also the authority exercised under the United States by which he was tried and convicted; that the authority of the United States is invoked to deprive him of his liberty, in a court established by Congress, and acting solely by Federal power; and that the question is, whether the authority exercised by the court under the act of 1882 is a valid authority, and within the *scope* of that act, because *the contention is that the court misconstrued the statute and acted beyond the authority which it conferred.* The authority exercised by the court in the trial and conviction of the plaintiff in error is not such an 'authority' as is intended by the act. The validity of the existence of the court, and its jurisdiction over the crime named in the indictments, and over the person of the defendant, are not drawn in question. *All that is drawn in question is whether there is or is not error in the administration of the statute.* The contention of the plaintiff in error would allow a writ of error from this court in every criminal case in a Territory where the prosecution is based on a statute of the United States; and, indeed, might go still further, for the authority of every court sitting in a Territory is founded on a statute of the United States. **FROM THE FACT THAT A GIVEN CRIMINAL CASE INVOLVES THE CONSTRUCTION OF A STATUTE OF THE UNITED STATES, IT DOES NOT FOLLOW THAT THE VALIDITY OF 'AN AUTHORITY EXERCISED UNDER THE UNITED STATES' IS DRAWN IN QUESTION.**

"There is a decision of this court on this point in *Bethell v. Demaret*, 10 Wall., 537. The 25th section of the Judiciary act of 1789 allowed a writ of error from this court to the highest court of a State, 'where is drawn in question the validity of a statute of, or an

authority exercised under, any State, on the ground of their being repugnant to the Constitution, treaties or laws of the United States, and the decision is in favor of such their validity' The case referred to was a writ of error to the highest court of a State, and it was contended that that court, in rendering the decision complained of, acted under the authority of the State, and so there was drawn in question an authority exercised under the State, which, in the particular case, impaired the obligation of a contract, and was repugnant to the Constitution of the United States, and the decision was in favor of the validity of such authority. To this view, this court, speaking by Mr. Justice Nelson, gave this answer: 'The authority conferred on a court to hear and determine cases in a State is not the kind of authority referred to in the 25th section; otherwise, every judgment of the Supreme Court of a State would be re-examinable under the section.'

* * * * * * * * * * * *

"We conclude, therefore, that we have no jurisdiction of these writs of error, and that they must be dismissed for that reason."

In *Linford v. Ellison*, 155 U. S., 503, the court held that a judgment of the Supreme Court of the Territory of Utah against the tax collector of a municipal corporation for fifty dollars, the value of property levied on by him for unpaid municipal taxes, rendered on the ground that a municipal corporation, which is a small village but has extensive limits, cannot tax farming lands for municipal purposes lying within the corporate limits but outside of the platted portion of the city and so far removed from the settled portion that the owner would receive no benefits from the municipal government, does not draw in question the validity of the organic law of the Territory. On motion to dismiss for want of jurisdiction, the court says (pp. 507-508) (the italics being ours):

"In the case at bar (7 Utah, 166), the Supreme Court declared that it had no reason to doubt the correctness of the former decision, and affirmed the judgment of the District Court. And, in accordance with the view that such taxation was *not within the power granted*, it was ruled that 'a municipal corporation, which is a small village, but having extensive limits, cannot tax farming lands for municipal purposes, lying within the corporate limits but outside of the platted portion of the city, and so far removed from the settled portion of the city that the owner will receive no benefits from the municipal government.'

"It is thus seen that the decision of the Supreme Court of the territory involved the *construction* of the organic law and the *scope of the authority* to legislate conferred upon the Territorial legislature; but that the *validity* of that authority and of the statute was not drawn in question. In order to give us jurisdiction of this appeal, the matter in dispute exclusive of costs must have exceeded the sum of $5,000, or else, without regard to the sum or value in dispute, the validity of a patent or copyright must have been involved, or the validity of a treaty or statute of or an authority exercised under the United States have been drawn in question. Act of March 3, 1885, c. 355, 23 Stat. 443. Confessedly, the matter in dispute here did not reach the requisite pecuniary value, and the validity of no patent or copyright was involved, nor was the validity of a treaty questioned; and, as just stated, we are of opinion that the validity of no statute of the United States, nor of an authority exercised under the United States, was drawn in question within the intent and meaning of the jurisdictional act."

In *Clough v. Curtis*, 134 U. S., 361, the court says (p. 370) that the words in the Act of March 3, 1885, the validity of a "statute of or an authority exercised under the United States"—

"do not embrace a case which depends only on a judicial construction of an act of Congress, there being no denial of the power of Congress to pass the act, or of the right to enjoy whatever privileges are granted by it. * * *"

In *Ferry v. King County*, 141 U. S., 668, the court said (p. 675):

"We have repeatedly held that the validity of a statute is not drawn in question every time rights claimed under such statute are controverted, nor is the validity of an authority every time an act done by such authority is disputed. *Snow v. United States*, 118 U. S., 346, 352; *Baltimore & Potomac Railroad v. Hopkins*, 130 U. S., 210; *Cook County v. Calumet & Chicago Canal and Dock Co.*, 138 U. S., 635.

"The validity neither of statute nor authority was primarily denied here and the denial made the subject of direct inquiry, nor was there any decision whatever against the validity of statute or authority.

"The writ of error is *dismissed*."

B. & P. Ry. Co. v. Hopkins, 130 U. S., 210, in error to the Supreme Court of the District of Columbia, was dismissed for the want of jurisdiction. It was an action in case by Hopkins for damages from nuisance; the railway company claimed that it possessed and exercised authority in virtue of grants from the United States to do all that it did in the premises, the validity of which authority, it was insisted, was denied by the court below; this court quoted at length the instructions given and refused, and also the several statutes invoked, reviewed the cases determining when the validity of an authority is or is not drawn in question, held that the validity of a statute or an authority exercised under the United States was not drawn in question, and dismissed the writ of error. That writ

was brought under the act of March 3, 1885, which excepts from the jurisdictional amount required, "any case wherein is involved the validity of any patent or copyright, or in which is drawn in question the validity of a treaty or statute of or an authority exercised under the United States,"—the exact language used in the statute under which the instant case is here. Among other things, this court said (p. 223):

> "* * * THE VALIDITY OF THE AUTHORITY MUST BE DRAWN IN QUESTION. THE DISTINCTION IS PALPABLE BETWEEN THE DENIAL OF THE VALIDITY OF THE AUTHORITY AND A DENIAL OF A TITLE, RIGHT, PRIVILEGE OR IMMUNITY CLAIMED UNDER IT."

Speaking to *Commercial Bank of Cincinnati v. Buckingham*, 5 How., 317, the court used this language in the *Hopkins* case (p. 223):

> "There both the prior and subsequent statutes were admitted to be valid under any construction of them, 'and therefore no construction placed by the state court on either of them, could draw in question its validity, as being repugnant to the Constitution of the United States.' *Bridge Proprietors v. Hoboken Co.*, 1 Wall., 116, 144."

And, in its consideration of *Lawler v. Walker*, 14 How., 149, the court, in the *Hopkins* case, said (pp. 223-224):

> "* * * The Supreme Court of Ohio, * * * only gave a construction to an act of Ohio, which neither of itself, nor by its application, involved in any way a repugnancy to the Constitution of the United States, by impairing the obligation of a contract."

Proceeding, in the *Hopkins* case, the court added (pp. 224, 225):

> "Whenever the power to enact a statute as it is by its terms, or is made to read by construction, is fairly open to denial and denied, the validity of such statute is drawn in question, but not otherwise.
>
> "In *Millingar v. Hartupee*, 6 Wall., 258, 261, 262, it was held that the word 'authority' stands upon the same footing with 'treaty' or 'statute'; and said the court, through Chief Justice Chase [as below quoted]; * * * * * * * * * * * * *
>
> "* * * In *Mining Company v. Boggs*, 3 Wall., 304, 310, which was an action of ejectment brought for the possession of certain mineral lands in California, where the defendant contended that he was in possession by virtue of an authority inferred from the general policy of the United States in relation to mines of gold and silver, Chief Justice Chase, speaking for the court, in dismissing the writ of error, said:
>
> "'The decision was, that no such license existed; and this was a finding by the court of a question of fact upon the submission of the whole case by the parties, rather than a judgment upon a question of law. It is the same case, in principle, as would be made by an allegation in defence to an action of ejectment, of a patent from the United States with an averment of its loss or destruction, and a finding by the jury that no such patent existed, and a consequent judgment for the defendant (plaintiff). Such a judgment would deny, not the validity, but the existence of the patent. And this court would have no jurisdiction to review it.'"

And the Court concludes its opinion in the *Hopkins* case as follows (p. 226):

> "* * * The right of the railroad company to establish freight stations or to lay as many tracks 'as its president and board of directors might deem necessary' was not questioned. But the court also

held that the company was not justified in occupying the public streets for the purpose of a freight yard as such, because the various statutes bearing upon the matter did not authorize such occupation. * * * The validity of the statutes and the validity of authority exercised under them, are, in this instance, one and the same thing; and 'the validity of a statute,' as these words are used in this act of Congress, refers to the power of Congress to pass the particular statute at all, and not to mere judicial construction as contradistinguished from a denial of the legislative power. In our opinion the validity of no act of Congress, or authority under the United States, was so drawn in question here as to give us jurisdiction, and therefore, as the amount of the judgment did not exceed five thousand dollars,

"*The writ of error must be dismissed.*"

In *Millingar v. Hartupee,* 6 Wall., 258, on motion to dismiss for the want of jurisdiction, the court said (pp. 261, 262):

"Something more than a bare assertion of such an authority seems essential to the jurisdiction of this court. The authority intended by the Act is one having a real existence, derived from competent governmental power. If a different construction had been intended, Congress would doubtless have used fitting words. The Act would have given jurisdiction in cases of decisions against claims of authority under the United States.

"In respect to the question we are now considering, 'authority' stands upon the same footing with 'treaty' or 'statute.' If a right were claimed under a treaty or statute, and on looking into the record, it should appear that no such treaty or statute existed, or was in force, it would hardly be insisted that this court would review the decision of a state court, that the right claimed did not exist.

* * * * * * * * * * * *

"In many cases the question of the existence of an authority is so closely connected with the question of its validity that the court will not undertake to separate them, and in such cases the question of jurisdiction will not be considered apart from the question upon the merits, or except upon hearing in regular order. But where, as in this case, the single question is not of the validity but of the existence of an authority and we are fully satisfied that there was, and could have been, no decision in the state court against any authority under the United States existing in fact, and that we have, therefore, no jurisdiction of the cause brought here by writ of error, we can perceive no reason for retaining it upon the docket.

"The motion for dismissal must, therefore, be allowed."

In *District of Columbia v. Gannon*, 130 U. S., 227, in error to the Supreme Court of the District of Columbia, on motion to dismiss for want of jurisdiction, the court says (p. 229):

"It is contended on behalf of the plaintiff in error that the validity of the authority conferred upon the District Commissioners by Congress is drawn in question in this suit.

"We do not agree with counsel in this view. The instructions above quoted involved the acts of Congress creating the District government only as bearing upon the question of the liability of the District for negligence in failing to keep the streets in repair, and by way of construction, and the validity of the acts themselves, or of the authority exercised under them, was not denied. The case of *Baltimore and Potomac Railroad Company v. Hopkins, ante*, 210, is decisive that jurisdiction cannot be maintained on this ground under such circumstances. The writ of error will therefore be *dismissed*."

In *Taylor v. Taft*, 203 U. S., 461, in error to the Court of Appeals of the District of Columbia, on motion to dismiss for want of jurisdiction, the court held that where a government employee does not deny the authority of the President or his representative to dismiss her, but only contends that her dismissal is illegal because certain rules and regulations of the civil service were not observed, the validity of an authority exercised under the United States is not drawn in question.

The relator was a clerk in the classified civil service of the United States, and employed in the War Department; by direction of the Secretary of War, she was called on to state whether she was the author of a certain newspaper article, and, if so, it was ordered that her attention should be invited to section 8 of civil service rule II, and that she be allowed three days in which to submit any answer or statement she might wish to make; she answered that she was the author of the article, but insisted that she had not been notified of any charge calling for answer under the rule; the Secretary entered an order dismissing her from the service, and filed a memorandum assigning as reason therefor the publication of the article; she then filed her petition for mandamus in the Supreme Court of the District of Columbia to compel the Secretary to restore her; the petition recited sections 3 and 8 of civil service rule II, and assigned as grounds of relief that the procedure was not in conformity with the executive regulations set out, in that no reasons for removal had been furnished her, and that the real reason for her removal was because of her political opinions and her expression of them.

In sustaining the motion to dismiss for want of jurisdiction, the court says (p. 463) that the right to a writ of error is given by section 233 of the code of the District of Columbia, 31 St. L., 1189, c. 854, 1227, which is quoted in full; and the court then says (p. 464):

"If this writ of error can be maintained it is on the ground that the validity of an authority exercised under the United States was drawn in question.

"The relator did not, however, question the authority of the President or his representatives to dismiss her, if the required formalities had been complied with. What she claimed was that there were certain rules and regulations of the civil service which were not observed in the matter of her dismissal, and that, therefore, such dismissal was illegal.

"But this contention did not draw in question the validity of an authority exercised under the United States, but the construction and application of regulations of the exercise of such authority."

The court then quotes *South Carolina v. Seymour*, 153 U. S., 353; *United States v. Lynch*, 137 U. S., 280; and thus concludes (p. 465):

"*Steinmetz v. Allen*, 192 U. S., 543, is not to the contrary, for there the validity of a rule constituting the authority of certain officers in the Patent Office was drawn in question.

"*Writ of error dismissed.*"

Moore v. Newcomb Motor Company, 216 U. S., 608, in error to the Court of Appeals of the District of Columbia to review a judgment directing that mandamus issue to compel the Commissioner of Patents to set aside certain orders made by him in the matter of certain pending applications for patents, was dismissed for want of jurisdiction on the authority of *Taylor v. Taft*, 203 U. S., 461; *United States v. Lynch*, 137 U. S., 280; and *B. & P. Ry. Co. v. Hopkins*, 130 U. S., 210, among other cases cited, and an application for *certiorari* was denied. *Per Curiam.*

In *Cook County v. Calumet & Chicago Canal & Dock Co.*, 138 U. S., 635, it was claimed that certain Illinois

swamp laws were not in harmony with certain swamp laws of Congress. On motion to dismiss for the want of jurisdiction, this court said (pp. 652-653, 654, 655):

> "* * * And the argument is that the validity of an authority exercised under the United States, namely, the action of the Land Department, was drawn in question, and that the decision was against its validity because against the validity of the alleged cancellation.
>
> "The trial court was not requested to hold the entry void because of cancellation, and we think the plaintiff's objection to the admission of the certificate in evidence, and its request for a ruling that the Egan entry was cancelled, and that such cancellation, 'in the absence of any facts or evidence showing the circumstances which led to its cancellation, must be presumed to have been based upon sufficient facts to authorize it,' did not draw the validity of the authority of the department in question within §709 Rev. Stat. upon which section our jurisdiction rests.
>
> **"THE VALIDITY OF A STATUTE IS NOT DRAWN IN QUESTION EVERY TIME RIGHTS CLAIMED UNDER SUCH STATUTE ARE CONTROVERTED, NOR IS THE VALIDITY OF AN AUTHORITY EVERY TIME AN ACT DONE BY SUCH AUTHORITY IS DISPUTED.**
>
> "The validity of the authority here was not primarily denied, and the denial made the subject of direct inquiry. *United States v. Lynch*, 137 U. S., 280; *Baltimore & Potomac Railroad v. Hopkins*, 130 U. S., 210.
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> * * * * * * * * * * * *
>
> "The Supreme Court did indeed say, in relation to this matter, that the commissioner had no authority to vacate the entry, and that any order that he might have made did not affect the rights of Egan, and cited to the proposition the case of *Brill v. Stiles*, 35 Illinois, 305, where it was held 'that the mere fact that an entry has been declared void by the commissioner of the general land office does not have the effect of vacating

the entry.' In other words, the court was of opinion that the commissioner could not, without notice, and arbitrarily, deprive a person of land lawfully entered and paid for, as was ruled in *Cornelius v. Kessel*, 128 U. S., 456, 461.

"But the expression of this view in construing the language of the state statute was not a decision against a title specially set up or claimed under the authority exercised under the United States, nor against the validity of such an authority.

* * * * * * * * * * * *

"We have carefully considered the record in the light of the elaborate arguments of counsel for plaintiff in error, but are constrained to hold that we have no jurisdiction to review the judgment of the state court, and the writ of error will, therefore, be *dismissed.*"

The following cases also show that the validity of an authority exercised under the United States is not drawn in question in the case at bar: *In re Craft*, 124 U. S., 370, 373-374; *Cameron v. United States*, 146 U. S., 533, 536; and *Abbott v. Tacoma Bank*, 175 U. S., 409, 412-413.

On Motion to Affirm.

On the merits, the questions upon which the disposition of this cause depends are so frivolous as not to need further argument, because they are foreclosed by *United States v. Grimaud*, 220 U. S., 506; *Williamson v. United States*, 207 U. S., 425; *United States v. Eaton*, 144 U. S., 677; *Morrill v. Jones*, 106 U. S., 466; and *United States v. Symonds*, 120 U. S., 46; which cases are cited in the opinion of the court below (Record, pp. 18-20).

If this court should determine that it has jurisdiction, it must also determine that this proceeding is under the regulation and not under the statute; and, as there is no pro-

vision in the statute for punishing a violation of the regulation, then the judgment or decree must be affirmed under the authorities just quoted.

The question of pleading disposed of by the Court of Appeals (Record, pp. 20-21) is so plainly decided rightly that further argument concerning it can not change the result.

CONCLUSION.

In conclusion, we submit that the writ of error and appeal should be dismissed for the want of jurisdiction, or the judgment or decree should be affirmed.

DANIEL W. BAKER,
JOSEPH C. SHEEHY,
FRANK J. HOGAN,
Attorneys for Defendant in Error and Appellee.

WASHINGTON, D. C., December 30, 1911.

Notice.

The United States of America, plaintiff in error and appellee, will please take notice that the foregoing motions and memorandum will be presented and submitted to the court on Monday, January 29, 1912, at twelve o'clock meridian, or as soon thereafter as counsel can be heard.

DANIEL W. BAKER,
JOSEPH C. SHEEHY,
FRANK J. HOGAN,
Attorneys for Defendant in Error and Appellee.

Acknowledgment of Service.

The service of copies of the foregoing motions and memorandum is hereby acknowledged this day of January, 1912.

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45; *N. Y., N. H. &c. R. R.* v. *Int. Com. Comm.*, 200 U. S. 361; *Smythe* v. *Fiske*, 23 Wall. 374; *Taylor* v. *United States*, 3 How. 197; *United States* v. *Five Boxes of Asafoetida*, 181 Fed. Rep. 561; *United States* v. *Hodson*, 10 Wall. 395; *United States* v. *Stowell*, 113 U. S. 1.

Even penal statutes should be construed to effectuate the legislative intent. *Northern Securities Co.* v. *United States*, 193 U. S. 197; *United States* v. *Harris*, 177 U. S. 305; *United States* v. *Lacher*, 134 U. S. 624.

The only alternative is that § 8 was left incomplete and the Secretaries were intended and authorized to fill in the outline. *Pickett* v. *United States*, 216 U. S. 456; *United States* v. *Hartwell*, 6 Wall. 385.

The power to make regulations having the force of law may be conferred by general language. *Bong* v. *Campbell Art. Co.*, 214 U. S. 236; *Buttfield* v. *Stranahan*, 192 U. S. 470; *Caha* v. *United States*, 152 U. S. 211; *Coopersville Creamery Co.* v. *Lemon*, 163 Fed. Rep. 145; *In re Kollock*, 165 U. S. 526; *Roughton* v. *Knight*, 219 U. S. 537; *United States* v. *Bailey*, 9 Pet. 238; *West* v. *Hitchcock*, 205 U. S. 80.

The power delegated to the Secretaries was constitutional. *Buttfield* v. *Stranahan*, *supra*; *Field* v. *Clark*, 143 U. S. 649; *In re Kollock*, 165 U. S. 526; *St. Louis & I. M. Ry.* v. *Taylor*, 210 U. S. 281; *Union Bridge Co.* v. *United States*, 204 U. S. 364; *United States* v. *Breen*, 40 Fed. Rep. 402; *United States* v. *Grimaud*, 220 U. S. 506.

The statement on the label of each package that no acetanilid was contained therein was false and misleading.

A statement may be misleading under § 8, although literally true. *Brina* v. *United States*, 179 Fed. Rep. 373; *Frank* v. *United States*, 192 Fed. Rep. 864; *Schraubstadter* v. *United States*, 199 Fed. Rep. 568; *United States* v. *Morgan*, 181 Fed. Rep. 587; *United States* v. *100 Cases of Apples*, 179 Fed. Rep. 985; *United States* v. *Scanlon*, 180 Fed. Rep. 485; *United States* v. *75 Boxes of Pepper*, 198

Fed. Rep. 934; *United States* v. *Ten Barrels of Vinegar*, 186 Fed. Rep. 399.

The statement was calculated to suggest that no derivative of acetanilid was contained in the tablets.

Section 8 was intended to cover just such deceptions as to identity. *United States* v. *Johnson*, 221 U. S. 488.

Mr. D. W. Baker, with whom *Mr. Joseph C. Sheehy*, *Mr. Frank J. Hogan* and *Mr. Wilton J. Lambert* were on the brief, for defendant in error and appellee:

The libel fails to charge a misbranding of the article therein within the meaning of the act of June 30, 1906.

The act gives neither authority nor power to the several Secretaries to promulgate a regulation requiring the name of the parent substance to be added.

The statement that no acetanilid is contained in the drug is neither misleading nor false. In support of this contention, see *443 Cases of Egg Product* v. *United States*, 226 U. S. 172; *United States* v. *Antikamnia Co.*, 37 App. D. C. 343; *Hipolite Egg Co.* v. *United States*, 220 U. S. 45; *United States* v. *Johnson*, 177 Fed. Rep. 313; *Huntington* v. *Attrill*, 146 U. S. 667; *Chouteau* v. *United States*, 102 U. S. 603; *Boyd* v. *United States*, 116 U. S. 616; *Coffey* v. *United States*, 116 U. S. 436; *Lees* v. *United States*, 150 U. S. 476; *Hepner* v. *United States*, 213 U. S. 111; *United States* v. *Harris*, 177 U. S. 305; *United States* v. *Lacher*, 134 U. S. 629; *Northern Securities Co.* v. *United States*, 193 U. S. 358; *Todd* v. *United States*, 158 U. S. 282; *Fozer* v. *United States*, 52 Fed. Rep. 919; *United States* v. *Traction Co.*, 34 App. D. C. 597; *Morrill* v. *Jones*, 106 U. S. 566; *United States* v. *200 Barrels of Whiskey*, 95 U. S. 751; *United States* v. *Three Barrels of Whiskey*, 77 Fed. Rep. 965; *Taylor* v. *Kercheval*, 82 Fed. Rep. 504; *United States* v. *Symonds*, 120 U. S. 46; *Williamson* v. *United States*, 207 U. S. 425; *Payne* v. *Railway Publishing Co.*, 20 App. D. C. 581; *United States* v. *Eaton*, 144 U. S. 677; *United States* v.

Sandfuhr, 145 Fed. Rep. 49; *United States* v. *Grimaud*, 220 U. S. 506; *Standard Oil Co.* v. *United States*, 222 U. S. 77; *United States* v. *George*, 228 U. S. 14; *Brown* v. *Piper*, 91 U. S. 37; *Manufacturing Co.* v. *Adkins*, 36 Fed. Rep. 554; *Engraving Co.* v. *Hoke*, 30 Fed. Rep. 444; *Lagler* v. *Bye*, 42 Ind. App. 592; *Diversey* v. *Smith*, 103 Illinois, 390; *Commonwealth* v. *Crane*, 158 Massachusetts, 219; *State* v. *Mann*, 2 Oregon, 241; *Brown* v. *State*, 131 Wisconsin, 543.

See page 3, Pharmacopœia of the United States of America, defining Acetanilid and Acetphenetidin, and page 8, United States Dispensatory, giving uses and effects of Acetanilid and Acetphenetidin.

See also Report No. 301 of Senate Committee on Manufactures, 58th Cong., 2d Sess., Jan. 15, 1904, accompanying Senate Bill 198, relating to "Adulteration of Foods, etc.," and containing statements of Dr. Wiley, of Department of Agriculture, relative to phenacetine (Acetphenetidin) and Acetanilide and hearings before Senate Committee, January 20, 1903, on H. R. 3109, being the Pure Food and Drugs Act, containing statements relative to the use of Acetanilid as an adulteration of or substitution for Acetphenetidin (Phenacetine).

An examination of 2350 judgments filed by the Agricultural Department up to February 1, 1913, shows that in no case, except the instant case, does the libel, indictment, or information charge a violation of a rule or regulation of the Department.

In No. 438, *The Ice Cream Case, United States* v. *Bishof*, there was charged a violation of the law and not any regulation of the Department.

Regulations have been held valid not under the Pure Food Act, but under act of Congress, March 3, 1903.

In *Hurdle Brand Holland Gin*, No. 807, the libel charged a violation of the law and not of any regulation. The court held the label was sufficient under the law.

The act of June 3, 1903, has been before the court on

various occasions, some of the decisions holding the power given valid, others that it is void. See *United States* v. *Frank*, 189 Fed. Rep. 195; *United States* v. *St. Louis Coffee Mills*, 189 Fed. Rep. 191; *Coopersville Creamery Co.* v. *Lemon*, 163 Fed. Rep. 145.

See also *United States* v. *11,150 Pounds of Butter*, 195 Fed. Rep. 665, holding that the Secretary of the Treasury cannot, by his regulations, alter or amend a revenue law. All he can do is to regulate the mode of proceeding to carry into effect what Congress has enacted. *St. Louis Bridge Co.* v. *United States*, 188 Fed. Rep. 191.

The admission of the Solicitor General that there cannot be a prosecution without this regulation is an admission that there cannot be an offense without this regulation, and therefore the regulation adds something to the statute that is not there. *McDermott* v. *Wisconsin*, 228 U. S. 115, distinguished.

The regulations in no sense have the force of law; at most they form a rule of conduct, which if not followed will place a person in a position where the Secretary will order the District Attorney to proceed under the law to prosecute for a violation of the law.

MR. JUSTICE MCKENNA delivered the opinion of the court.

Libel for the seizure and condemnation of certain drugs under the provisions of the act of Congress of June 30, 1906, commonly known as the Food and Drugs Act, c. 3915, 34 Stat. 768.

The libel alleges that the drugs are in the possession and custody of The Wholesale Drug Exchange, a body corporate, at a numbered place in the City of Washington.

The drugs, it is alleged, are intended to be used for the cure and mitigation and prevention of diseases of man. They are described as follows:

"Twenty packages, more or less, of said drug, labelled and branded as follows: 'Antikamnia Tablets, Contain 305 grains of acetphenetidin, U. S. P. per ounce, Guaranteed by the Antikamnia Chemical Company, under the Food and Drugs Act, June 30, 1906, U. S. Serial Number 10. The Antikamnia tablets in this original ounce package contain no acetanilid, antifebrin, antipyrin, morphine, opium, codein, heroin, cocaine, alpha or beta eucaine, arsenic, strychnine, chloroform, cannabis indica, or chloral hydrate, Antikamnia tablets five grains. One ounce Antikamnia Tablets. Manufactured in the United States of America by the Antikamnia Chemical Co., St. Louis, U. S. A.'

"Also seventy other packages, more or less, of said drug, labelled and branded as follows: 'Antikamnia and Codein Tablets. Contain 296 grains acetphenetidin, U. S. P. per ounce. Contain 18 grains sulp. codein per ounce. Guaranteed by the Antikamnia Chemical Company, under the Food and Drugs Act, June 30, 1906. U. S. Serial Number 10. The Antikamnia and Codein tablets in this original ounce package contain no acetanilid, antifebrin, antipyrin, morphine, opium, heroin, cocaine, alpha or beta eucaine, arsenic, strychnine, chloroform, cannabis indica, or chloral hydrate. One ounce Antikamnia and Codein Tablets. Manufactured in the United States of America by the Antikamnia Chemical Co., St. Louis, U. S. A.'

"Also ten other packages, more or less, of said drug, labelled and branded as follows: 'Antikamnia and Quinine Tablets. Contain 165 grains acetphenetidin, U. S. P. per ounce. Guaranteed by the Antikamnia Chemical Company under the Food and Drugs Act, June 30, 1906, U. S. Serial Number 10. The Antikamnia and Quinine Tablets in this original ounce package contain no acetanilid, antifebrin, antipyrin, morphine, opium, codein, heroin, cocaine, alpha or beta eucaine, arsenic, strychnine,

chloroform, cannabis indica, or chloral hydrate. One ounce Antikamnia and Quinine Tablets. Manufactured in the United States of America by the Antikamnia Chemical Co., St. Louis, U. S. A.'"

The ground of confiscation and condemnation alleged is that all of the packages of the drugs contain a large quantity and proportion of acetphenetidin, which, it is alleged, is a derivative of acetanilid, and that under the provisions of the act of Congress and of the regulations lawfully made thereunder it is provided and required that the label on each of the packages shall bear a statement that the acetphenetidin contained therein is a derivative of acetanilid; and yet, it is alleged that each and all of the packages fail to comply with such provisions.

It is also alleged that the packages are further misbranded, in that the labels thereon are false and misleading, for the reason that each and all of them bear the statement that no acetanilid is contained therein, and that the statement imports and signifies that there is no quantity of any derivative of acetanilid contained in the drug.

A warrant of arrest was issued upon which the marshal duly made return that he had arrested twenty packages of Antikamnia tablets, ten packages of Antikamnia quinine tablets and sixty-three packages labeled "Antikamnia and Codein Tablets," and otherwise duly executed the warrant.

The Antikamnia Chemical Company, appellee and defendant in error, alleging itself to be the owner of the drugs, petitioned to be made a defendant in the libel. The petition was granted, and the company thereupon filed the exceptions to the libel. The exceptions negative in detail the charges of the libel and assert conformity in the labelling of the packages to the act of Congress of June 30, 1906, 34 Stat. 768, p. 770, quoting its eighth section as follows: ". . . . or if the package fail to bear a statement on the label of the quantity or proportion of

any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilid, or any derivative or preparation of any such substances contained therein." And it is averred that the act does not provide that there should be added to any derivative of any of the substances contained therein the name of the parent substance, and the act cannot be added to or enlarged by requiring the company to add to the name of a known article, the fact that the article is a derivative of any of the substances mentioned in the act. It is averred, therefore, that the packages are not misbranded and that the statement on the labels that no acetanilid is contained therein is in no way false or misleading because the libel does not allege that there is acetanilid in the packages, and, therefore, the statement instead of being false and misleading is, according to the allegations of the libel, true.

The exceptions were sustained and the libel dismissed.

It was stipulated that Food Inspection Decision No. 112, issued January 27, 1910 by the United States Department of Agriculture was considered by the court upon the hearing of the cause and should be included in and be considered part of the record on appeal.

The decision quotes § 8 of the act, states that the Attorney General, in an opinion rendered January 15, 1909, held that a derivative is a substance so related to one of the specified substances "that it would be rightly regarded by recognized authorities in chemistry as obtained from the latter 'by actual or theoretical substitution,' and it is not indispensable that it should be actually produced therefrom as a matter of fact;" further that the labelling of derivatives, as prescribed by § 8, is a proper subject conferred upon the Department by § 3, and that a rule or regulation requiring the name of the specified substance to follow that of the derivative would be in harmony with the general purpose of the act, and an

appropriate method by which to give effect to its provisions.

In conformity to this opinion, Regulation 28 of the Rules and Regulations for the enforcement of the Food and Drugs Act was amended as follows: ". . . Acetanilide (antifebrine, phenylacetamide). Derivatives—Acetphenetidine, . . . (g) In declaring the quantity or proportion of any of the specified substances the names by which they are designated in the act shall be used, and in declaring the quantity or proportion of the derivatives of any of the specified substances, in addition to the trade name of the derivative, the name of the specified substance shall also be stated, so as to indicate clearly that the product is a derivative of the particular specified substance."

The decree of the Supreme Court of the District dismissing the libel was affirmed by the Court of Appeals.

The case is not in very broad compass, though the arguments of counsel are somewhat elaborate. The libel is prosecuted for the condemnation of one hundred packages of Antikamnia tablets as being misbranded in violation of the Food and Drugs Act of June 30, 1906, c. 3915, 34 Stat. 768. The tablets contain acetphenetidin and the labels so state, and the proportion of the substance. It is a derivative of acetanilid, but the labels do not so state but do state that the tablets contain no acetanilid. And these omissions, it is contended by the Government, constitute a violation of the statute and of Regulation No. 28 as amended. The chemical company contends that the first statement is not required by the law and that the second statement is true, and therefore cannot be false or misleading.

Preceding the discussion of these contentions a question of jurisdiction is presented by the chemical company and a motion to dismiss is made on the ground that only the construction of the statute is involved in the decision of

the court below. The company also moves for an affirmance of the judgment on the ground that the appeal is frivolous. *Contra* the Government contends that the Court of Appeals held invalid the regulation requiring the name of the primary substance as well as that of the derivative to be stated on the label; and that there is not only drawn in question, but so far denied, an authority exercised under the United States. We concur in this view. The validity of the regulation was and is denied. Its validity may, indeed, rest on the statute, but so did the validity of the rule of the Patent Office passed on in *Steinmetz* v. *Allen*, 192 U. S. 543. We there said (p. 556) of a rule of practice established by the Commissioner of Patents under a section of the Revised Statutes, "It thereby became a rule of procedure and constituted, in part, the powers of the primary examiner and Commissioner. In other words, it became an authority to those officers, and, necessarily, an authority 'under the United States.' Its validity was and is assailed by the plaintiff in error. We think, therefore, we have jurisdiction, and the motion to dismiss is denied." *United States ex rel. Taylor* v. *Taft, Secretary of War*, 203 U. S. 461, is not in antagonism to this ruling. In that case the relator was dismissed from the public service by an order of the Secretary of War as representative of the President. She sought restoration by mandamus. It was denied and she brought the case to this court on the ground that the validity of an authority exercised under the United States was drawn in question. Dismissing the case, this court said that as she did not question the authority of the President or his representative to dismiss her but contended only that certain rules and regulations of the civil service had not been observed, the validity of an authority exercised under the United States was not drawn in question but only the construction and application of regulations of the exercise of such authority. On p. 465 it was said

Steinmetz v. *Allen* was not to be contrary, "for there the validity of a rule constituting the authority of certain officers in the Patent Office was drawn in question."

Motion to dismiss is denied.

Joined with the motion to dismiss, we have seen, was a motion to affirm on the ground that the question of the authority of the Secretaries to make the regulation is frivolous in view of the decisions in *United States* v. *Grimaud*, 220 U. S. 506; *Williamson* v. *United States*, 207 U. S. 425 and other cases. How far this contention is tenable will be developed as we proceed with the consideration of the act and the power of the Secretaries under it.

The purpose of the act is to secure the purity of food and drugs and to inform purchasers of what they are buying. Its provisions are directed to that purpose and must be construed to effect it.

Section 3, 34 Stat. 768, gives the Secretary of the Treasury, the Secretary of Agriculture and the Secretary of Commerce and Labor, power to "make uniform rules and regulations for carrying out the provisions" of the act and the power to collect specimens of foods and drugs offered in interstate and foreign commerce. It adopts the definitions of the United States Pharmacopoeia or National Formulary and provides (§ 8, 34 Stat., p. 770) that the term "misbranded" as used in the act "shall apply to all drugs . . . the package or label of which shall bear any statement, design or device regarding such article, or the ingredients or substances contained therein which shall be false or misleading in any particular." And, further, in case of drugs, an article shall be deemed to be misbranded "if the package fail to bear a statement on the label of the quantity or proportion" of certain enumerated substances "or acetanilid, or any derivative or preparation of any such substances contained therein."

These are the applicatory provisions. How are they to be construed?

First, as to the power of the Secretaries. It is undoubtedly one of regulation only—an administrative power only—not a power to alter or add to the act. The extent of the power however, must be determined by the purpose of the act and the difficulties its execution might encounter. The fact that a council of three Secretaries of governmental departments was given power to make the rules and regulations for the execution of the law shows how complex the matters dealt with were considered to be, and the care that was necessary to be taken to guard against their defeat or perversion. The composition of drugs is a matter of technical skill, their denomination often by words of scholastic origin, conveying no meaning to the uninformed, their uses and abuses learned only by experience, beneficial or evil. It was this experience that the law sought to avail itself of and to avail itself against the ever increasing powers of the laboratory or the disguises of a technical nomenclature. Hence the provision of the law that the term "drug" as used in the act shall include all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary for internal or external use, and hence also the provision that a drug or food product is misbranded in case it fails to bear a statement on the label of the quantity or proportion of certain enumerated substances, including acetanilid, "or any derivative or preparation of any such substance contained therein." Experience had demonstrated the quality of those substances, their effects had become common knowledge; their names, therefore, were all the warning it was necessary for the law to give. But derivatives of them might, probably would, be of their quality, so derivatives of them were to be guarded against, and the law hence further provided that the labels on them should state the "quantity or proportion" of "any derivative or preparation" of them. This much is clear—there is no obscurity in the words and purpose of the law. The

query then occurs, such being the words and purpose, if the quantity or proportion of the substances or any derivative or preparation of them must be stated, is it administrative of the law or additive to it to require by regulation that not only the name of the derivative or preparation be stated but from what substance derived or of what it is a preparation? It certainly cannot be said that the purpose of the law is not exactly fulfilled by the regulation. If it fulfills the purpose of the law it cannot be said to be an addition to the law, unless, indeed, it can be contended that the law provided a means for its defeat by the easy device of mysterious names. There is illustration in the present case. What information does the use of the word "acetphenetidin" convey to anybody of its good or evil origin? If it be said that the like question may be asked of any of the primary substances, we reply that they are the precautions of the law and adopted as such because they had demonstrated themselves, the value of their use, the detriment of their abuse, and it was believed that their names would carry no deception.

But let us turn from the power of the Secretaries to the law itself and inquire if it needs the assistance of a regulation. It is the contention of the Government that it does not, that its requirement that the primary substances should be labelled and that their derivatives should be labelled means, necessarily, that it should be stated of what they are the derivatives to make the warning of the labels complete. A great deal of what we have said in discussing the power of the Secretaries applies to this contention and supports it. The purpose of the law is the ever insistent consideration in its interpretation. The purpose is to prevent the surreptitious sale of certain noxious drugs or their derivatives, the latter supposedly partaking of the quality of parent article and as effective of evil consequences. This being the purpose, did the law leave it unexecuted? We cannot attribute to it such

defect, and a serious defect it might be. Nor can we consider as a case of omission that which involves so definitely the mischief which was intended to be redressed and which is fairly within the language of the law. And we say this without regard to the various illustrations contained in the Government's brief of the deceptions which can be practiced by using the name of the derivative alone, for the chemical company insists that we may not, in the absence of allegations and proof, look for knowledge in the encyclopedias, or medical lexicons or to trade practices for trade disguises, actual or possible. It is not necessary to enter upon the challenged ground. The law furnishes its own tests of what the labels should reveal, and we may grant, for the argument's sake, as contended, that it has penal character; but this does not mean that it should not be given its reasonable intendment. There is no hardship in this either to the manufacturer or the seller of drugs. They surely know what they make or vend—know whether it is primary or of what a derivative—and the law requires only that they put their knowledge on the labels for the information of purchasers. No serious burden is thereby imposed on honest business. Indeed, it makes the label on the packages an assurance as well as a warning and benefits all concerned, manufacturer, seller and purchaser. And this is the interest of the public health.

Decree reversed and cause remanded with direction to reverse the decree of the Supreme Court and remand the cause with direction to overrule the exceptions to the libel.